

**PUBLIC VERSION**

and sworn testimony, therefore shows that Cercacor accurately allocated certain R&D projects as related to the rainbow® sensors.

The evidence demonstrates that Cercacor's R&D investments in the rainbow® sensors are quantitatively and qualitatively significant.

Cercacor's largest project has been the rainbow® technology. For example, from 2005-2020, Cercacor spent a total net R&D expense of about [REDACTED], with about [REDACTED] of that dedicated to rainbow® technology. Tr. (Hammarth) at 524:16-525:5; CDX-0008C.002 (summarizing CX-0633C); CX-0633C. Moreover, as previously discussed, [REDACTED] of the investment in rainbow® technology was incurred in the U.S. Tr. (Hammarth) at 525:6-8; *see Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83, EDIS Doc. ID 709073 (Apr. 28, 2020) (finding quantitative significance where "all, *i.e.*, 100 percent, of Kyocera's R&D and engineering expenditures relating to complainant's [DI products] occurs in the United States."), *vacated and remanded on other grounds*, 22 F.4th 1369 (Fed. Cir. 2022); *Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing the Same*, Inv. No. 337-TA-1223, Initial Determination at 60, EDIS Doc. ID 756910 (Oct. 22, 2021) (finding quantitative significance where 100% of research and development activities were based in the United States), *not reviewed in relevant party by Comm'n Notice*, EDIS Doc. ID 762554 (Feb. 4, 2022). Other than criticizing Complainants' other quantitative comparisons, or arguing that Complainants' expenditures are overstated and unreliable, Apple does not specifically rebut Complainants' contention that Cercacor's R&D investments are quantitatively



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significant.<sup>137</sup> *See, e.g.* RIB at 278; RRB at 174-75. The evidence therefore demonstrates that Cercacor's domestic investments in R&D labor for rainbow® are quantitatively significant.

Cercacor's domestic R&D investments for the rainbow® sensors are also qualitatively significant. Cercacor's R&D effort related to the rainbow technology has been a large part of its business, and again, was incurred entirely in the U.S. *See, e.g., Certain Percussive Massage Devices*, Inv. No. 337-TA-1206, Comm'n Op. at 10-15, EDIS Doc. ID 759545 (Jan. 4, 2022) (affirming finding that complainant satisfied the economic prong of the domestic industry requirement and finding qualitative significance, in part, because complainant's domestic industry products "would not exist without [its] domestic operations and spending" because it "designed and developed the DI Products in the United States"). In addition, not only has it been Cercacor's largest project in terms of R&D spend, as explained above, but over the years, Cercacor has employed the [REDACTED] of its employees to work on rainbow®. *See* CDX-0015C.015 (summarizing CX-0633C) (showing that Cercacor has dedicated between [REDACTED] and [REDACTED] of its employees to rainbow®); CX-0633C. In addition to Cercacor's domestic R&D labor investments, Masimo has also made domestic investments in R&D labor for rainbow®. *See* Tr. (Young) at 499:15-500:7; CX-0644C. Lastly, it is worth noting that Masimo also manufactures important components of the rainbow® sensors, semiconductor LEDs and optical packages of emitters and detectors, at its Hudson, New Hampshire facility in the U.S., distinguishing Complainants from a mere importer. *See* Tr. (Young) at 507:7-15; *see also* CX-0636C; CX-0638C; *see Certain Toner Supply Containers and Components Thereof (II)*, Inv. No. 337-TA-1260, Comm'n Op. at 11-12, EDIS Doc. ID 777011 (Aug. 3, 2022) (finding qualitative

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<sup>137</sup> Apple's arguments disputing quantitative significance focus on Complainant's cost of goods (COGS) analysis. *See* RIB at 278. The undersigned, however, is not relying on that analysis in finding quantitative significance.



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significance where a domestic industry is based on “core manufacturing activities,” affirming an initial determination finding that “[s]uch activities have long been recognized as a domestic industry within the meaning of section 337.”).

In opposition, Apple argues that “Complainants ignore that rainbow® product revenues generally comprise only [REDACTED] of Masimo’s total product revenues in 2020.” *See* RIB at 278. Apple, however, fails to explain why this would be a more appropriate comparison under these circumstances. *See, e.g., Certain Carburetors and Prods. Containing Such Carburetors, Inv. No. 337-TA-1123, Comm’n Op. at 28 (Oct. 28, 2019)* (“Significance is based on the marketplace conditions regarding the articles protected by the Asserted Patents. The fact that a complainant may have substantial sales of other products is not pertinent to this analysis.”).

Accordingly, the undersigned finds that Complainants have demonstrated significant employment of labor or capital with respect to the rainbow® sensors. As discussed above, however, Complainants have not satisfied the domestic industry requirement with respect to the ’127 patent because the current rainbow® sensors have not been shown to practice any claim of the ’127 patent.

**IX. CONCLUSIONS OF LAW**

Based on the foregoing, and the record as a whole, it is the undersigned’s final initial determination that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof by reason of infringement of claims 24 and 30 of the ’648 patent. There has been no violation of the statute with respect to the asserted claims of the ’501 patent, the ’502 patent, the ’745 patent, or the ’127 patent.



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This determination is based on the following conclusions of law:

1. The Commission has subject matter jurisdiction over this investigation.
2. The Accused Products have been imported into the United States, sold for importation, and/or sold within the United States after importation.
3. The Commission has *in rem* jurisdiction over the Accused Products.
4. The Accused Products infringe claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.
5. The technical prong of the domestic industry requirement has been satisfied for claim 12 of the '501 patent, claim 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.
6. Claim 12 of the '501 patent, claim 28 of the '502 patent, and claim 12 of the '648 patent are invalid.
7. The '501 patent, '502 patent, and '648 patent have not been shown to be unenforceable.
8. The economic prong of the domestic industry requirement has been satisfied with respect to the '501 patent, the '502 patent, and the '648 patent.
9. The Accused Products have not been shown to infringe claims 9 or 27 of the '745 patent.
10. The technical prong of the domestic industry requirement has been satisfied for claim 18 of the '745 patent.
11. Claims 9, 18, and 27 of the '745 patent have not been shown to be invalid.
12. The '745 patent has not been shown to be unenforceable.
13. The economic prong of the domestic industry requirement has been satisfied with respect to the '745 patent.
14. The Accused Products have not been shown to infringe claim 9 of the '127 patent.
15. The technical prong of the domestic industry requirement has been satisfied for claim 9 of the '127 patent.
16. Claim 9 of the '127 patent has not been shown to be invalid.
17. The economic prong of the domestic industry requirement has not been satisfied with respect to the '127 patent.



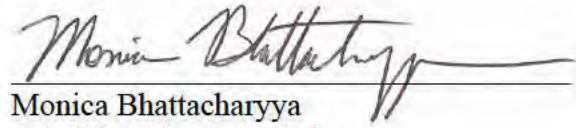
**PUBLIC VERSION**

The undersigned hereby certifies the record in this investigation to the Commission with the undersigned's final initial determination. Pursuant to Commission Rule 210.38, the record further comprises the complaint and exhibits thereto, and the exhibits attached to the parties' summary determination motions and the responses thereto. 19 C.F.R. § 210.38(a).

Pursuant to Commission Rule 210.42(h)(2), this initial determination shall become the determination of the Commission 60 days after the service thereof, unless a party files a petition for review pursuant to Commission Rule 210.43(a), the Commission orders its own review pursuant to Commission Rule 210.44. 19 C.F.R. § 210.42(h)(2).

This initial determination is being issued with a confidential designation pursuant to Commission Rule 210.5 and the protective order in this investigation. Within 10 days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this final initial determination with any proposed redactions consistent with the manner specified by Ground Rule 1.9.<sup>138</sup> The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

**SO ORDERED.**

  
Monica Bhattacharyya  
Administrative Law Judge

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<sup>138</sup> Redactions should be limited to avoid obscuring the reasoning underlying the decision. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, explaining why each proposed redaction meets the definition for confidential business information in 19 C.F.R. § 201.6(a).



**APPX23473**  
**ENTIRELY REDACTED**



**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya  
Administrative Law Judge**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**COMPLAINANTS' PETITION FOR REVIEW OF THE FINAL INITIAL  
DETERMINATION ON VIOLATION OF SECTION 337**



[REDACTED]

Accordingly, the ID's obviousness analysis regarding '501 Patent Element [1E] legally erred by ignoring the entirety of the claimed requirements and should be reversed. If the Commission reverses and upholds the validity of '501 Claim 12, the result would be a Section 337 violation for the '501 Patent.

**B. Issue No. 2: Though the ID Correctly Found Nonobviousness of '502 Patent Claim 28, the ID Legally Erred with regard to Element [28G]**

If the Commission reviews any part of the ID's obviousness analysis for '502 Patent Claim 28, it should reverse the ID's finding that Lumidigm discloses a "plurality of transmissive windows" as recited by Element [28G]. ID at 131.

Element [28G] recites "a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings." Apple provided no evidence that a POSITA would have been motivated to modify Lumidigm's faceplate into multiple windows. The ID found that "Lumidigm discloses a single window [such as a fiber-optic faceplate]," but made no finding regarding a motivation to modify Lumidigm's single faceplate into multiple windows. *Id.* at 131. Instead, the ID observed that "Warren suggests that 'a person of skill would know that you *could do* an individual faceplate for each of the individual openings as a means to provide light but still optimize the process.'" *Id.* at 131 (quoting Tr. (Warren) 1221:16-1222:25). But as the ID recognizes elsewhere, Warren's testimony "of what [a POSITA] *could theoretically do* is insufficient to clearly and convincingly show that Lumidigm discloses this arrangement, or provide a reason for [a POSITA] to modify Lumidigm to do so." *Id.* at 121; *see, e.g., Adidas AG*, 963 F.3d at 1359 (obviousness inquiry does not ask what a POSITA "could" do, but instead asks what "they *would have been motivated to do*"). Thus, the ID committed legal error by finding that Lumidigm satisfied the requirements of Element [28G] based on Warren's testimony about what a POSITA "could do."

[REDACTED]

The ID also made no findings on whether a POSITA would have had a reasonable expectation of success in modifying Lumidigm's face plate into multiple windows. ID at 131. Warren identified other references with windows, but Apple provided no evidence that a POSITA *would have modified* Lumidigm's face plate into multiple windows with a reasonable expectation of success. RIB at 84-85; *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012) (obviousness finding requires clear and convincing evidence that a POSITA "would have had a reasonable expectation of success" in modifying the prior art). Thus, the lack of any reasonable expectation of success analysis confirms the ID legally erred to the extent it found Lumidigm satisfied Element [28G].

C. **Issue No. 3: Though the ID Correctly Found Nonobviousness of the '502 and '648 Patents, the ID Legally Erred and Made Clearly Erroneous Factual Findings in its Analysis of the Protrusion Comprising a Convex Surface Elements of the '502 and '648 Patents ('502 Patent Elements [19C], [28E]; '648 Patent Elements [8D], [20C])**

As explained above regarding '501 Patent Element [1C] ("a protrusion comprising a convex surface"), the ID erred in finding a POSITA would have been motivated to modify Lumidigm to add a protrusion comprising a convex surface. *Supra* Section IV.A.3. The ID relies on that same erroneous analysis in its analysis of the "protrusion" elements of the remaining asserted claims of the Poeze Patents. ID at 120 (analysis for '502 Patent Element [19C]), 130 ('502 Patent Element [28E]), 139 ('648 Element Patent [8D]), 141 ('648 Element Patent [20C]). Thus, if the Commission reviews any part of the ID's obviousness analysis for '502 Patent Claims 22 or 28, or '648 Patent Claims 12, 24, or 30, it should reverse any findings regarding the "protrusion" elements of those claims—'502 Patent Elements [19C] and [28E], and '648 Patent Elements [8D] and [20C]—for the reasons discussed above for '501 Patent Element [1C].



**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya  
Administrative Law Judge**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**COMPLAINANTS' SUMMARY OF PETITION FOR REVIEW OF THE FINAL  
INITIAL DETERMINATION ON VIOLATION OF SECTION 337**

Pursuant to 19 C.F.R. § 210.43(b)(2), Complainants Masimo Corporation and Cercacor Laboratories, Inc. (collectively, “Masimo” or “Complainants”) hereby submit this Summary of Masimo’s Petition for Review of the Final Initial Determination on Violation (ID) issued by Administrative Law Judge Monica Bhattacharyya on January 10, 2023. While the ID correctly found a Section 337 violation for Claims 24 and 30 of the ’648 Patent, the record establishes a broader violation for additional claims and patents due to Apple’s infringement and the deficiencies in Apple’s defenses. Accordingly, Masimo petitions for review of the issues below:

**I. THE POEZE PATENTS (’501, ’502, AND ’648 PATENTS)**

**A. Issue No. 1: The ID Legally Erred and Made Clearly Erroneous Factual Findings in Concluding ’501 Patent Claim 12 Would Have Been Obvious**

The ID concluded that Lumidigm, combined with Seiko 131, renders obvious ’501 Patent Claim 12. ID at 89-113. One straightforward example of a legal error in the obviousness analysis is the ID’s failure to address the entirety of Element [1E]. That element requires that the “opaque lateral surface” be “configured to avoid light piping through the protrusion.” *Id.* at 107-108. The ID never addressed the limitation regarding light piping “through the protrusion” and instead improperly relied on Lumidigm’s discussion of light reflecting off the user’s tissue. *Id.* at 107.

[REDACTED]

reason not to modify Lumidigm.

If the Commission reverses any of these findings and upholds the validity of '501 Claim 12, the result would be a Section 337 violation for the '501 Patent.

**B. Issue No. 2: Though the ID Correctly Found Nonobviousness of '502 Patent Claim 28, the ID Legally Erred With Regard To Element [28G]**

The ID legally erred by finding that Lumidigm satisfied the requirements of Element [28G] based on Warren's testimony about what a POSITA "could do." ID at 131. The ID also legally erred because Apple provided no evidence that a POSITA would have modified Lumidigm's face plate into multiple windows with a reasonable expectation of success (RIB at 84-85), and the ID made no findings regarding reasonable expectation of success for such a modification. ID at 131.

**C. Issue No. 3: Though the ID Correctly Found Nonobviousness of the '502 and '648 Patents, the ID Legally Erred and Made Clearly Erroneous Factual Findings in its Analysis of the Protrusion Comprising a Convex Surface Elements of the '502 and '648 Patents ('502 Patent Elements [19C], [28E]; '648 Patent Elements [8D], [20C])**

The ID relied on its erroneous findings regarding '501 Patent Element [1C] ("a protrusion comprising a convex surface") in its obviousness analysis of the "protrusion" elements of the remaining asserted claims of the Poeze Patents. ID at 120, 130, 139, 141. Thus, if the Commission reviews any part of the ID's obviousness analysis for the asserted claims of the '502 and '648 Patents, it should reverse any findings regarding the "protrusion" elements of those claims.

**D. Issue No. 4: The ID Legally Erred and Made Clearly Erroneous Factual Findings in Giving Insufficient Weight to the Objective Evidence Showing Nonobviousness of the Claimed Inventions of the '501, '502, and '648 Patents**

In evaluating commercial success, the ID required evidence of a "significant nexus" before considering the evidence of commercial success of Apple's infringing product (Apple Watch Series 6). ID at 155-156. That requirement was legal error because no such heightened standard exists in order for the evidence of commercial success to be objective evidence of nonobviousness. The ID compounded that legal error by making several erroneous factual findings. ID at 154-156.



**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of  
CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**RESPONDENT APPLE INC.'S PETITION FOR REVIEW OF  
THE INITIAL DETERMINATION OF VIOLATION OF SECTION 337**

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**TABLE OF ABBREVIATIONS**

<b>'501 patent</b>	U.S. Patent No. 10,912,501
<b>'502 patent</b>	U.S. Patent No. 10,912,502
<b>'648 patent</b>	U.S. Patent No. 10,945,648
<b>'745 patent</b>	U.S. Patent No. 10,687,745
<b>'127 patent</b>	U.S. Patent No. 7,761,127
<b>“Poeze patents”</b>	U.S. Patent No. 10,912,501, U.S. Patent No. 10,912,502, and U.S. Patent No. 10,945,648
<b>Tr.</b>	Hearing Transcript
<b>Dep.</b>	Deposition Transcript
<b>JX</b>	Joint Exhibit
<b>CX</b>	Complainants' Exhibit
<b>CPX</b>	Complainants' Physical Exhibit
<b>CDX</b>	Complainants' Demonstrative Exhibit
<b>RX</b>	Respondent's Exhibit
<b>RPX</b>	Respondent's Physical Exhibit
<b>RDX</b>	Respondent's Demonstrative Exhibit
<b>CPHB</b>	Complainants' Pre-Hearing Brief
<b>CIB</b>	Complainants' Corrected Initial Post-Hearing Brief (7/14/22)
<b>CRB</b>	Complainants' Reply Post-Hearing Brief
<b>RPHB</b>	Respondent's Pre-Hearing Brief
<b>RIB</b>	Respondent's Second Corrected Initial Post-Hearing Brief (9/2/22)
<b>RRB</b>	Respondent's Corrected Reply Post-Hearing Brief (9/14/22)

**TABLES OF CLAIM ELEMENT IDENTIFIERS**

U.S. Patent No. 10,912,501	
Identifier	Claim/Element
Claim 12	
<b>[1 Preamble]</b>	A user-worn device configured to noninvasively measure a physiological parameter of a user, the user-worn device comprising:
<b>[1A]</b>	at least three light emitting diodes (LEDs);
<b>[1B]</b>	at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;
<b>[1C]</b>	a protrusion arranged over the interior surface, the protrusion comprising a convex surface and
<b>[1D]</b>	a plurality of openings extending through the protrusion and positioned over the three photodiodes,
<b>[1E]</b>	the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion; and
<b>[1F]</b>	one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.
<b>[12]</b>	The user-worn device of Claim 1, wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape.

## U.S. Patent No. 10,912,502

Identifier	Claim/Element
<b>Claim 22</b>	
<b>[19 Preamble]</b>	A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:
<b>[19A]</b>	a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);
<b>[19B]</b>	four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
<b>[19C]</b>	a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;
<b>[19D]</b>	optically transparent material within each of the openings; and
<b>[19E]</b>	one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.
<b>[20]</b>	The user-worn device of claim 19 further comprising a thermistor.
<b>[21]</b>	The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.
<b>[22]</b>	The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.



**U.S. Patent No. 10,912,502**

<b>Identifier</b>	<b>Claim/Element</b>
<b>Claim 28</b>	
<b>[28 Preamble]</b>	A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:
<b>[28A]</b>	a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;
<b>[28B]</b>	a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
<b>[28C]</b>	four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
<b>[28D]</b>	a thermistor configured to provide a temperature signal;
<b>[28E]</b>	a protrusion arranged above the interior surface, the protrusion comprising: a convex surface;
<b>[28F]</b>	a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and
<b>[28G]</b>	a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;
<b>[28H]</b>	at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities;
<b>[28I]</b>	one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal;
<b>[28J]</b>	a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;
<b>[28K]</b>	a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user;
<b>[28L]</b>	a storage device configured to at least temporarily store at least the measurement; and
<b>[28M]</b>	a strap configured to position the user-worn device on the user.

**U.S. Patent No. 10,945,648**

<b>Identifier</b>	<b>Claim/Element</b>
<b>Claim 12</b>	
<b>[8 Preamble]</b>	A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:
<b>[8A]</b>	a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
<b>[8B]</b>	a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
<b>[8C]</b>	four photodiodes;
<b>[8D]</b>	a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;
<b>[8E]</b>	a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;
<b>[8F]</b>	a separate optically transparent window extending across each of the openings;
<b>[8G]</b>	one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;
<b>[8H]</b>	a housing; and
<b>[8I]</b>	a strap configured to position the housing proximate tissue of the user when the device is worn.
<b>[12]</b>	The user-worn device of Claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation.
<b>Claim 24</b>	
<b>[20 Preamble]</b>	A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:
<b>[20A]</b>	a plurality of light emitting diodes (LEDs);
<b>[20B]</b>	at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;
<b>[20C]</b>	a protrusion comprising a convex surface and
<b>[20D]</b>	a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and
<b>[20E]</b>	one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.
<b>[24]</b>	The user-worn device of Claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping.

U.S. Patent No. 10,945,648	
Identifier	Claim/Element
Claim 30	
[20 Preamble]	A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:
[20A]	a plurality of light emitting diodes (LEDs);
[20B]	at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;
[20C]	a protrusion comprising a convex surface and
[20D]	a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and
[20E]	one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.
[30]	The user-worn device of Claim 20, wherein the protrusion further comprises one or more chamfered edges.



U.S. Patent No. 10,687,745	
Identifier	Claim/Element
Claim 9	
<b>[1 Preamble]</b>	A physiological monitoring device comprising:
<b>[1A]</b>	a plurality of light-emitting diodes configured to emit light in a first shape;
<b>[1B]</b>	a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue;
<b>[1C]</b>	a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light;
<b>[1D]</b>	a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;
<b>[1E]</b>	a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue;
<b>[1F]</b>	and a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal.
<b>[9]</b>	The physiological monitoring device of claim 1, wherein the physiological parameter comprises oxygen saturation.

U.S. Patent No. 10,687,745	
Identifier	Claim/Element
Claim 18	
<b>[15 Preamble]</b>	A physiological monitoring device comprising:
<b>[15A]</b>	a plurality of light-emitting diodes configured to emit light proximate a wrist of a user;
<b>[15B]</b>	a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a tissue measurement site on the wrist of the user when the physiological monitoring device is in use;
<b>[15C]</b>	a light block having a circular shape;
<b>[15D]</b>	a plurality of photodiodes configured to detect at least a portion of the light emitted from the plurality of light-emitting diodes after the light passes through the light diffusing material and a portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block,
<b>[15E]</b>	wherein the plurality of photodiodes are further configured to output at least one signal responsive to the detected light, and
<b>[15F]</b>	wherein the plurality of light-emitting diodes and the plurality of photodiodes are arranged in a reflectance measurement configuration;
<b>[15G]</b>	wherein the light block is configured to optically isolate the plurality of light-emitting diodes from the plurality of photodiodes by preventing at least a portion of light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the portion of the tissue measurement site;
<b>[15H]</b>	a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal; and
<b>[15I]</b>	wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor.
<b>[18]</b>	The physiological monitoring device of claim 15, wherein the physiological parameter comprises oxygen saturation.

U.S. Patent No. 10,687,745	
Identifier	Claim/Element
Claim 27	
<b>[20 Preamble]</b>	A system configured to measure one or more physiological parameters of a user, the system comprising: a physiological monitoring device comprising:
<b>[20A]</b>	a plurality of light-emitting diodes configured to emit light in a first shape;
<b>[20B]</b>	a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue;
<b>[20C]</b>	a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light;
<b>[20D]</b>	a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;
<b>[20E]</b>	a light block configured to prevent at least a portion of light from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue; and
<b>[20F]</b>	a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal; and
<b>[20G]</b>	a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data.
<b>[27]</b>	The system of claim 20, wherein at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength.



U.S. Patent No. 7,761,127	
Identifier	Claim/Element
Claim 9	
[7 Preamble]	A physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient, the physiological sensor comprising:
[7A]	a thermal mass;
[7B]	a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass,
[7C]	the sources having a corresponding plurality of operating wavelengths,
[7D]	the thermal mass disposed within the substrate;
[7E]	a temperature sensor thermally coupled to the thermal mass and
[7F]	[the temperature sensor] capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature; and
[7G]	a detector capable of detecting light emitted by the light emitting sources after tissue attenuation,
[7H]	wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths.
[9]	The physiological sensor according to claim 7 wherein the temperature sensor comprises a thermistor.

## I. INTRODUCTION

Complainants Masimo Corporation and Cercacor Laboratories Inc. have sought to leverage old ideas to eliminate Apple’s latest-generation Watch products from the U.S. market, and thereby improve the prospects for Masimo’s own future watch products—which, when the Complaint was filed, did not exist and were still in development. There is no proper basis for an exclusion order.

The Administrative Law Judge’s Initial Determination (“ID”) correctly identified a range of fundamental flaws in Complainants’ positions, and for four of the five asserted patents, the ID rightly found no violation. The remaining two claims of the last patent in the “Poeze Patent” family also provide no basis for an exclusion order. The Poeze Patent family claims long-known configurations of generic components for noninvasive physiological measurement devices. These types of devices have existed for decades, but Complainants were forced to claim such well-known components because they were trying to stretch a twelve-year-old patent specification from the clinical medical-device field (in which they built their business) to the consumer-products field (in which Complainants have had no meaningful presence). Claiming “lowest common denominator” components from both fields was the only way to attempt such a stretch.

Yet, even after drafting claims directed to generic components, Complainants have still failed to cover the Accused Apple Watches. Apple’s engineers invested significant time and effort to independently develop hardware and software for a pulse oximeter—i.e., “Blood Oxygen feature”—in Apple Watch that would meet Apple’s exacting design standards to provide wide range of consumers with another useful wellness feature while retaining the aesthetic appeal that is Apple’s hallmark. The Blood Oxygen feature in Apple Watch reflects Apple’s own ideas and innovations, not Masimo’s patents.

The narrow ground on which the ID found a violation was two dependent claims (24 and 30) of the '648 patent. Thus, of the **103 claims** that Complaints originally asserted, less than **2%** were found to be violated. But the ID erred by finding an exclusion order could rest on the two '648 claims. The Poeze Patent family has profound invalidity problems—in parallel IPR proceedings involving the larger family, only 1 out of over 300 challenged claims has been found patentable.<sup>1</sup> This overwhelming IPR failure rate (over 99% invalidation) speaks to the fundamental problems arising from Complainants' efforts to stretch their patent portfolio to try to reach Apple's products. And, for the two '648 claims on which the ID found a violation, the problems go far beyond invalidity, to noninfringement and lack of domestic industry.

In short, although the ID correctly found no violation for four of the five asserted patents here, the ID erred with respect to the '648 patent—and not just on factual issues, but in the interpretation and application of basic legal principles. The Commission should correct those errors on that one patent—which, if corrected, would require a ruling of no violation. Accordingly, Apple seeks review of the following issues:

- The ID's errors in misapplying Federal Circuit precedent to find two asserted claims of the '648 patent not invalid, including (1) the ID's legal error in requiring the prior art to enable measuring of blood oxygen ***on the wrist*** when no asserted claim contains such a limitation, the '648 patent does not disclose such a measurement, and, under the ID's standard, the '648 patent itself could not enable such a measurement; and (2) the ID's legal errors in limiting its analysis of the prior art to specific embodiments and imposing an improper "bodily incorporation" standard, rather than considering the art as a whole, when deciding whether a POSITA would have been motivated to include separate openings over photodiodes as the asserted claims of the '648 patent recite;

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<sup>1</sup> Petitions for *inter partes* review of the patents asserted in this case, including the '648 patent, were filed after the hearing and are currently pending.

- The ID’s errors in relying on evidence not related to the actual physical articles proffered by Complainants for their alleged domestic industry, to find the technical prong satisfied for the ’648 (and related) patents;
- The ID’s erroneous constructions of “over”/“above” and “openings”/“through holes,” without which it could not have found infringement of the ’648 patent; and
- The ID’s errors with respect to the economic prong, including its aggregation of expenditures for multiple distinct groups of asserted domestic industry products to find the economic prong satisfied with respect to the ’648 (and other) patents.

Correcting any ***one*** of the four issues will result in a finding of no violation.

To the extent the Commission takes review of issues for any of the other four patents, the Commission should also take review and correct findings that would have provided additional bases for no violation for those patents. Accordingly, Apple contingently seeks review of issues related to the other four patents as set forth herein.

To be clear, the simplest path to bring this Investigation to conclusion is for the Commission to limit its review to the ’648 patent, correct the errors—including the legal errors—in the ID’s analysis of claims 24 and 30, and find no violation. This Complaint never should have been brought in this agency, and the Commission should now bring this case to a close.

## **II. BACKGROUND**

### **A. The Parties**

#### **1. Masimo & Cercacor**

Masimo Corporation is a medical technology company based in Irvine, California. DocID 770692. Since its founding, Masimo has focused on the clinical setting where it derives the vast majority of its revenues. Tr. [Kiani] 140:8-14; *see also* RX-1204C [Kiani Dep.] 99:15-23 (estimating Masimo’s clinical products account for over [REDACTED] of revenue). Cercacor, also based in Irvine, California, was spun off from Masimo in 1998. Tr. [Kiani] 93:12-20. Cercacor conducts



research and development in the field of non-invasive patient monitoring technologies for use in clinical settings and licenses its technology to Masimo. Complaint ¶¶ 19-20.

## **2. Apple**

Respondent Apple is a California corporation with its principal place of business in Cupertino, California. Joint Stipulation of Facts (May 13, 2022) (Doc. ID 770692) Apple designs and manufactures a variety of consumer electronic devices, including personal and tablet computers, mobile communication devices, portable digital music and video players, and smart watches. Apple is, and has been for decades, one of the world's leading technology firms. *See, e.g.,* Tr. [Waydo] 933:12-934:10 (describing Apple's approach to technology development).

### **B. Procedural History**

Complainants filed their Original Complaint on June 30, 2021 and their First Amended Complaint ("Complaint") on July 7, 2021.<sup>2</sup> The Commission instituted this Investigation on August 13, 2021. The evidentiary hearing was conducted June 6-10, 2022. The ALJ issued her ID on January 10, 2023. The ID found no violation as to 101 out of 103 originally asserted claims, but a violation as to '648 patent claims 22 and 30.

## **III. STANDARD OF REVIEW**

Under 19 C.F.R. §§210.43(b)(1) and (d)(2), the Commission will grant a petition and order review if (1) a legal conclusion is erroneous or without governing precedent, rule or law; (2) a finding or conclusion of material fact is clearly erroneous; or (3) the petition raises a policy matter that the Commission deems appropriate to address. A factual finding is "clearly erroneous" when the tribunal, after reviewing all relevant evidence, is left with the definite and firm conviction that a

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<sup>2</sup> Complainants inadvertently filed the confidential version of the First Amended Complaint publicly on July 7, 2021. After Apple alerted Complainants to their error, the confidential version was removed and refiled on July 12, 2021. DocID 746514.

mistake has been committed. *See JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1329 (Fed. Cir. 2005); *see also Miller v. Mercy Hosp., Inc.*, 720 F.2d 356, 361 (4th Cir. 1983).

**IV. THE COMMISSION SHOULD REVIEW ERRORS WITH RESPECT TO THE '648 PATENT FAMILY ("POEZE PATENTS"), THE CORRECTION OF ANY ONE OF WHICH WOULD RESULT IN NO VIOLATION IN THIS CASE.**

Three of the asserted patents, U.S. Patent Nos. 10,912,501 ("501 patent"), 10,912,502 ("502 patent"), and 10,945,648 ("648 patent") (collectively, "Poeze patents") share a common specification. While the ID properly found no violation as to the '501 or '502 patent or claim 12 of the '648 patent, it erred in finding a violation for two claims of the '648 patent.<sup>3</sup>

*First*, the ID committed clear factual and legal errors in its analysis of invalidity for claims 24 and 30 of the '648 patent. In particular, the ID committed legal error by requiring Apple's asserted prior art reference, U.S. Patent No. 7,620,212 ("Lumidigm"), to enable a device capable of measuring blood oxygen *at the wrist*, even though neither the asserted Poeze claims nor their patent specifications require or even describe taking a measurement at the wrist. Indeed, Complainants' CEO and named inventor, Joseph Kiani, conceded that Masimo did not even possess the "feasibility" of a device that could take a blood oxygen measurement at the wrist until years after the patents were filed. It was error for the ID to require the prior art to disclose more than the asserted patents—this directly contradicts governing Federal Circuit precedent.

The ID also legally erred in its finding that Lumidigm does not disclose "separate openings extending through the protrusion" over the photodiodes. The ALJ improperly limited her analysis of obviousness to two figures in Lumidigm and *sua sponte* dismissed it based on an argument that

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<sup>3</sup> The ID found '501 claim 12 invalid as obvious, '502 claim 28 invalid for lack of written description, and '648 claim 12 invalid for lack of written description. ID 336. Because '502 claim 28 was the only identified domestic industry claim for the '502 patent, the ID also found no violation based on '502 claim 22. The ID accordingly premised its finding of a violation solely on '648 claims 24 and 30. ID 335.

Complainants and their expert *never* made. That was legal error because other portions of Lumidigm—on which Apple relied—explicitly teach the use of *any* number of sensors in *any* arrangement. The ID also rejects an alternative combination under the wrong legal standard. Apple’s technical expert, Dr. Steven Warren, testified—and Complainants’ never disputed—that POSITA have understood since the 1960s that including separate openings over each photodiode is fundamental to allow the desired light—i.e., light that has passed through the tissue—to reach the detectors while providing optical blocking of unwanted light.

***Second***, Complainants failed to show that any purported domestic-industry article practices the claims of the Poeze patents, either now or at the relevant time when the Complaint was filed. At base, Complainants had to show they possessed a physical article at the time of the Complaint that practices the ’648 patent, including by having the ability to measure blood oxygen. If Complainants actually possessed such a device, it presumably would have been an easy task for them to come forward with direct evidence, including testing of those actual devices and source code showing they perform the requisite functionality. Complainants provided *zero* such proof of their own asserted DI articles. Rather, the direct evidence shows all but one of the proffered devices were created or altered after the Complaint was filed. The ID’s finding that the technical prong was satisfied erroneously hinged its conclusion on what it called “circumstantial evidence” that Complainants had other prototypes that may have been capable of measuring blood oxygen. That is, the ID rested on evidence of unidentified devices not offered as the DI articles. Moreover, the ID did not cite any evidence confirming the blood oxygen measurements allegedly taken by those other devices were even taken on the wrist as the ALJ required of the prior art. But in any event, those other prototypes were not the asserted articles put forth by Complainants, nor was there any evidence that those other prototypes satisfied the other limitations of the asserted claims.

It was accordingly legal error to find the technical prong satisfied based on this evidence. Moreover, the ID erred in finding the technical prong satisfied for a domestic industry “in the process” of being established “even if” the prototypes do not practice the asserted claims.

*Third*, notwithstanding Complainants’ best efforts to stretch their clinical ideas to cover the consumer Apple Watch when drafting the asserted claims, they did not reach far enough. The ID erroneously dismissed Apple’s contentions that Apple Watch does not infringe because it is not configured to measure a physiological parameter with a protrusion “*over*” or “*above*” the photodiodes, and does not have “*openings*” extending or provided “*through the protrusion*” or “*through holes*,” as required by the asserted claims based on flawed claim constructions that Complainants did not even offer before the hearing.

*Finally*, the ID’s analysis of the economic prong of the domestic industry requirement with respect to the Poeze patents was both legally improper and based on clearly erroneous findings of fact. Specifically, the ID’s analysis of Masimo’s expenditures on multiple Masimo Watch prototypes *in the aggregate* rather than by requiring Complainants to allocate the expenditures among each of the different devices was contrary to Commission precedent that requires allocation to specific DI products. Moreover, despite rejecting more than [REDACTED] of claimed expenditures for lack of reliability, the ALJ still improperly credited [REDACTED] of dollars in claimed expenditures for which the only documentary support is a set of made-for-litigation spreadsheets. The Commission has never sustained a finding that the economic prong has been satisfied based on such scant and uncorroborated evidence—and the Commission should not permit the ID finding to stand here.



For these and the additional reasons set forth below, the Commission should conduct a review to correct these errors in the ID’s analysis of the ’648 patent. Correction of the ID’s errors in any one of the four categories above will result in a finding of no violation in this case.

#### A. The Poeze Specification

The Poeze patents were filed on September 24, 2020—more than twelve years after the provisional application to which they claim priority —and only a week after the release of Apple Watch Series 6 on September 18, 2020. JX-001 [’501 patent]; JX-002 [’502 patent]; JX-003 [’648 patent]; Tr. 138:1-13 (Apple Watch release dates); CX-1287 at 10; Tr. [Cromar] 1028:5-10. The Poeze claims each recite a “user-worn device” for measuring a physiological parameter with a combination of multiple light emitting diodes (“LEDs”), multiple photodiodes, and a protrusion “comprising a convex surface.” Significantly, the embodiments disclosed in the shared specification are all traditional *finger*-clip sensors for measuring *glucose*. JX-001 at 10:2-11:1 (“this disclosure is described primarily in the context of a finger measurement site”); 7:27-30 (“the present disclosure relates to an interface for a noninvasive glucose sensor”); Tr. [Warren] 1200:23-1201:13. The specification contains no specific teaching on measuring oxygen saturation. Instead, the specification focuses on glucose, and mentions only briefly that the claimed invention also can be used to measure other blood analytes including oxygen, carbon monoxide, and hemoglobin. *See, e.g.*, JX-001 at 7:27-30, 10:30-39, 10:62-65, 12:26-59, 16:44-51, 30:3-9. The specification also contains no teachings at all on measurements at the wrist. Instead, it identifies multiple potential measurement sites, including the “finger, toe, hand, foot, ear, forehead, or the like,” and *nowhere* mentions taking a measurement at the wrist. *E.g.*, JX-001 [’501 patent] 15:21-23, 10:64-11-2. Tr. [Warren] 1201:19-24; *see also* Tr. [Madisetti] 1385:22-24.

## B. The Commission Should Grant Review Of Invalidity.

The ID correctly found that the prior art discloses or renders obvious almost all limitations of the asserted claims of the Poeze patents and that several asserted claims are invalid as obvious or for failure to meet the written description requirement. The ID makes critical legal errors, however, that form the basis of the finding of a violation of claims 24 and 30 of the '648 patent. Correcting for the clear legal errors in the ID's obviousness analysis of just two limitations would result in a finding of no violation.<sup>4</sup>

*First*, the ID found the asserted claims of the '648 patent not obvious based on its conclusion that the Lumidigm prior art reference does not enable taking an "oxygen saturation" measurement "*at the wrist*."<sup>5</sup> ID 113-117. But *none* of the Poeze claims recites or requires taking a measurement at the wrist—nor could they, because the Poeze specification does not

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<sup>4</sup> Patents in the Poeze patent family have been the subject of numerous inter partes review proceedings, in which the PTAB has found more than 300 claims unpatentable; only a single claim has survived. Apple requests the Commission take judicial notice of the Final Written decisions reflecting this failure rate. *See* Final Written Decisions in IPR2020-01520 (Paper 39); IPR2020-01521 (Paper 33); IPR2020-01536 (Paper 43); IPR2020-01537 (Paper 43); IPR2020-01538 (Paper 43); IPR2020-01539 (Paper 41); IPR2020-01713 (Paper 31); IPR2020-01714 (Paper 34); IPR2020-01715 (Paper 33); IPR2020-01716 (Paper 35); IPR2020-01722 (Paper 29); IPR2020-01733 (Paper 33); IPR2020-01737 (Paper 33); IPR2021-00193 (Paper 30); IPR2021-00195 (Paper 32); IPR2021-00208 (Paper 32); IPR2021-00209 (Paper 32). It is well-established that IPR proceedings are suitable for judicial notice. *See, e.g.,* Certain Infotainment Sys., Components Thereof, & Automobiles Containing the Same, Inv. No. 337-TA-1119, Order No. 52 at 1, 2019 WL 4744857 at \*1 (Sept. 23, 2019) ("USPTO decisions are matters of public record and 'capable of accurate and ready determination by resort to sources whose accuracy could not reasonably be questioned.'"). The ALJ erred in her decision not to take notice of those decisions. *See* Order No. 57. But in any event, the Commission is an independent body free to take judicial notice of its own accord. Further, following the hearing in this Investigation, Apple petition for inter partes review of the asserted Poeze, '127 and '745 patents; Apple respectfully requests the Commission take notice of those proceedings also, initiation decisions on which are expected to issue shortly. *See* IPR Nos. IPR2022-01271; IPR2022-01272; IPR2022-01273; IPR2022-01274; IPR2022-01275; IPR2022-01276; IPR2022-01299; IPR2022-01300; IPR2022-01291; IPR2022-01292; IPR2022-01465; IPR2022-01466.

<sup>5</sup> Emphasis added throughout this brief unless otherwise noted.

disclose or describe such a measurement. In fact, Masimo's CEO and named inventor Joseph Kiani conceded that Masimo did not possess the "feasibility" of a device that could take a blood oxygen measurement at the wrist until *years after* the priority date. Tr. [Kiani] 150:3-12 (Q. Sir, you were not in possession as of 2008 of the engineering solution to putting a pulse oximeter in a watch, correct? 6 A. Well, not all of the -- not all the components of it, but some of it, yeah, that's what this patent shows. Q. Sir, you could not build a watch with a pulse oximeter in it; you did not have possession of that idea in 2008, correct? A. We did not have feasibility until maybe 2016, 2017."). Thus, the ID faulted the prior art for lacking something that Masimo itself did not possess, that it did not describe in the Poeze Patent specification, and that therefore cannot be a requirement of the claims.

The ID reached this illogical conclusion by committing multiple legal errors, namely: (1) reading a new limitation into the claims (a measurement "at the wrist") and (2) imposing an enablement standard on the prior art that the asserted patents could not meet.

This illogical conclusion is flatly contrary to governing law. For patent claims that cover a range of embodiments—like the Poeze patent claims drawn to a category of "user-worn devices,"—several black-letter legal principles apply. To invalidate such a claim, a prior art reference need only disclose and enable one embodiment within the scope of the claims. *In re Theresa*, 720 Fed. Appx. 634, 637 (Fed. Cir. 2018) ("When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.") (citing *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001)); *In re Guess*, 347 Fed. Appx. 558, 560 (Fed. Cir. 2009) ("A disclosure of a species anticipates a claim to a genus."). In contrast, the patentee has the duty to provide enabling written description support for all embodiments covered by the claims—

a failure to demonstrate possession and enablement of the full scope of the claims (*i.e.*, the “genus” of embodiments) requires invalidation of the claims. *See, e.g., Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999-1000 (Fed. Cir. 2008) (“Because the asserted claims are broad enough to cover both movies and video games, the patents **must enable both embodiments.**”); *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007 (“[T]o fulfill the enablement requirement, the specification must enable the full scope of the claims.”) In assessing the descriptiveness and enablement of any particular prior art reference, it is legal error to impose a more stringent standard on the prior art than is applied to an asserted patent. Indeed, the opposite is true, because the asserted patent(s) specification must contain a more robust disclosure that describes and enable **all** claimed embodiments, and the prior art need only describe and enable **one** embodiment. *See, e.g., In re Publicover*, 813 F. App’x 527, 532 (Fed. Cir. 2020) (rejecting argument that prior art was “too sparse to adequately explain to a skilled artisan” how to implement disputed limitation because the asserted patent was “just as sparse”); *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (rejecting argument that prior art was not enabling where patent owner “did not provide the type of detail in his specification that he now argues is necessary in prior art references”); *In re Paulsen*, 30 F.3d 1475, 1481 (Fed. Cir. 1994) (rejecting argument that prior art was not enabling where “under the enablement standard that AST would have us apply to Yokoyama, the ’456 patent itself would be non-enabling.”).

Here, the ID committed legal and factual error that effectively turned this doctrine on its head. Contrary to the governing law, the ID imposed a higher burden on the prior art than on the Poeze patents. In particular, the ID required that the Lumidigm prior art enable a wrist-worn embodiment capable of measuring blood oxygen, within the larger category of “user-worn devices” with such capability claimed by the patents, even though none of the Poeze claims recites

or requires taking a measurement at the wrist. The ID then held that the prior art did not provide enabling description of that wrist-worn embodiment. This was incorrect as a matter of fact – the expert record was *unrebutted* that a POSITA would have known how to take a measurement at the wrist from Lumidigm’s disclosure. More fundamentally, it was incorrect as a matter of law—it was flatly inconsistent with the basic legal principles set out above. Indeed, if the ID were correct that the prior art (1) had to enable measuring blood oxygen on the wrist (which the claims do not require) and (2) did not do so, then under the ALJ’s own logic, the Poeze Patent claims would be invalid for lack of an enabling written description—because the Poeze patents contain no description of wrist-worn devices capable of measuring blood oxygen.

*Second*, the ID further erred in finding that Lumidigm does not render obvious the required “separate openings” in the protrusion over each of four photodiodes. In doing so, the ID again committed legal error by ignoring the teachings of the prior art as a whole. The ID rejected Apple’s single reference obviousness contentions based on an argument Complainants did *not* make—that the “array” of four+ photodiodes in Figures 7A and 7B of Lumidigm could have been covered by a single opening rather than multiple, separate openings. But Lumidigm’s disclosure and Apple’s obviousness argument were not confined to Figures 7A and 7B; to the contrary, Lumidigm explicitly discloses that its sensor can “include *any number and arrangement* of photodiodes.” RX-0411 at 6:54-56, 9:30-34. By ignoring the teachings of Lumidigm *as a whole*, the ID reached a nonsensical result: it found that Lumidigm renders obvious a protrusion with “a *plurality of openings* extending through the protrusion and positioned over *three* photodiodes” as required by claim 12 of the ’501 patent (ID 106 (finding a POSITA “would have reason to modify the optical surface 39 of Lumidigm to form a ‘protrusion comprising a convex surface’ *and* that the modified optical surface “would extend over the photodiodes and the openings over them”))), but then



concluded the use of the same openings over *four* photodiodes would not have been obvious. Moreover, the ID summarily dismissed Apple’s alternative obviousness combination by finding a POSITA would not have “reason to combine the *specific structures* of Cramer with Lumidigm.” ID 121. Not so: obviousness does not depend on the combination of specific embodiments but on the teachings of the prior *art as a whole*.

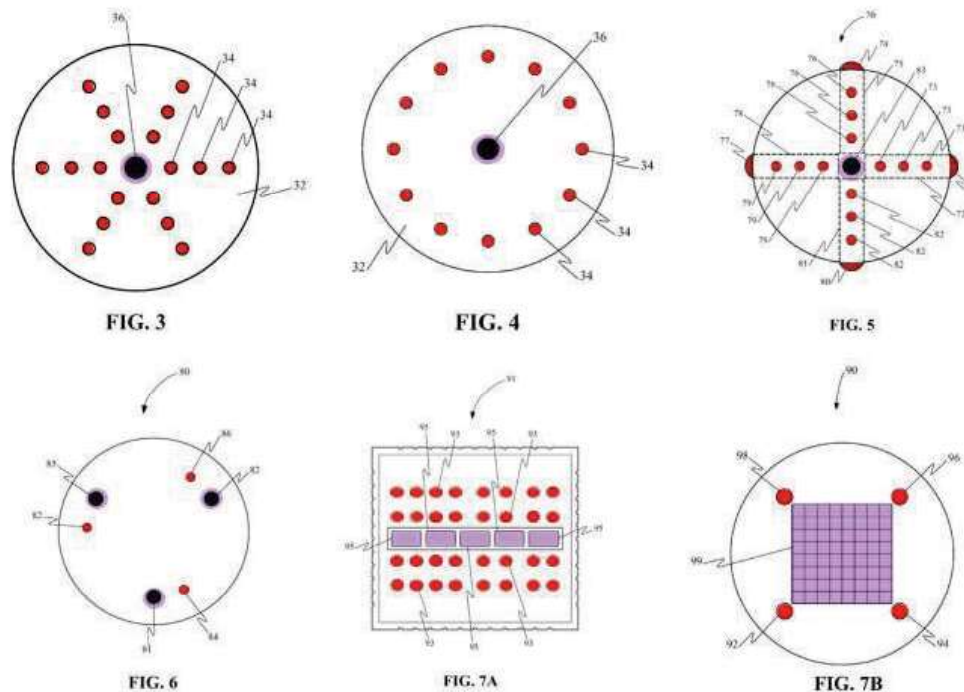
The bottom line is that for the only two claims in this case for which the ID found a violation, the ID analyzed two claim limitations in a way that was contrary to governing law. Correcting for the legal errors on these limitations compels invalidating the two claims—and invalidating these two claims would result in no violation in this Investigation.

**1. The ID Correctly Found That Lumidigm Discloses Or Renders Obvious Almost All Limitations Of The Asserted Poeze Patent Claims.**

Lumidigm, filed on August 20, 2003, is indisputably prior art to the Poeze patents. ID 88. The ID correctly found that Lumidigm discloses or renders obvious almost all limitations of the Poeze Patent claims. ID 80-144.

As Apple’s expert, Dr. Steven Warren, confirmed, Lumidigm’s specification provides “a collation of what was known about [at] the time” about optical sensor heads for spectrometry purposes. Tr. [Warren] 1204:1-17. Lumidigm’s purported novelty focuses on detecting the liveness of tissue, but Lumidigm repeatedly teaches that its light-based sensors also could be used to measure physiological parameters such as “oxygenation and/or hemoglobin levels in the blood.” RX-0411 at 19:16-28; *see also id.* at 4:25-29 (stating invention may measure “concentration of a substance in the tissue of the individual, such as concentration of alcohol, bilirubin, or hemoglobin, among others”); 10:11-21 (detected “features include oxy- and deoxy-hemoglobin bands”); Tr. [Warren] 1204:8-17, 1205:1-11, 1215:18-1216:9; *see also* Tr. [Rowe] 1142:10-1148:4.

Lumidigm explains that its sensor head can include any number and arrangement of *light sources*, including LEDs, in any variety of wavelengths. RX-0411 at 6:38-53, 8:33-9:11, 9:26-34. Lumidigm further confirms that the sensor can include any number and any arrangement of *detectors*, including photodiodes, as “a single element, a plurality of discrete elements, or a one- or-two dimensional array of elements.” *Id.* at 6:54-63, 9:12-45, 9:52-57. Lumidigm illustrates examples of such arrangements in Figures 3 through 7B (shown below with LEDs in red and photodiodes in purple), but notes that “other numbers and arrangements” of sources and detectors “may alternatively be used” and that “[m]any variants exist”:



*Id.* at Figs. 3-7B, 9:30-45; Tr. [Warren] 1204:18-12:05:11; Tr. [Rowe] 1148:5-19.<sup>6</sup>

Lumidigm explicitly confirms that the head of its sensor (i.e., the part in contact with the user’s tissue) can have a “*compound curvature on the optical surface* to match the profile of a

<sup>6</sup> Throughout this brief, Apple has added color to Lumidigm’s figures to highlight the relevant components.

device in which it is mounted, to incorporate ergonomic features that allow for good optical coupling with the tissue being measured, or for other technical or stylistic reasons.” RX-0411 at 7:58-63. Lumidigm also discloses that its sensor can be incorporated into a “portable electronic device,” along with other standard components such as processors, memory, and wireless communication interfaces, and provides as examples user-worn wristwatches, key fobs, cell phones, and personal digital assistants. RX-0411 at Figs. 8A-E, Fig. 9, 3:35-37, 12:56-13:14, 11:60-12:2; Tr. [Warren] 1205:12-1206:7; Tr. [Rowe] 1152:4-25.

## 2. The ID Erred In Finding That Lumidigm Does Not Disclose Measuring Oxygen Saturation.

The asserted ’648 claims each require a “*user-worn* device” that can measure “oxygen” or “oxygen saturation.”<sup>7</sup> The ID erred by finding these limitations not satisfied based on errors of law and fact when it concluded that Lumidigm does not enable a *wrist*-worn device for measuring oxygen.

**First**, the ID focused on the wrong issue—whether Lumidigm enables taking an oxygen saturation measurement “*at the wrist*.” ID 115-118. This is irrelevant as *none* of the Poeze claims recites or requires taking a blood oxygen measurement *at the wrist*—nor could they, because the Poeze specification does not disclose or describe such a measurement. In fact, Masimo’s CEO and named inventor Joseph Kiani conceded that Masimo did not possess the “feasibility” of a user-worn device that could take a blood oxygen measurement at the wrist until *years after* the provisional applications were filed (Tr. [Kiani] 147:3-10, 150:3-12 (confirming Masimo “did not have feasibility” to make such a device “until maybe 2016, 2017”)).

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<sup>7</sup> Asserted claims 22 and 28 of the ’502 patent similarly require a “user-worn” device that can measure “oxygen” or “oxygen saturation.” The ID erred in its obviousness analysis of those claims for the same reasons as stated herein.

The ID accordingly erred as a matter of law by requiring Lumidigm to enable a claim limitation that does not exist (a blood oxygen measurement “at the wrist”). While the ID acknowledged that the Federal Circuit in *In re Kumar* has stated that a *prima facie* case of obviousness may be rebutted with a showing that the prior art is not enabling (ID 115), the ID improperly ignores that the relevant standard under *Kumar* is whether “the prior art method would not produce or would not be expected to produce **the claimed subject matter**.” *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005); *id.* (rebuttal to obviousness “may take the form of evidence that the prior art does not **enable the claimed subject matter**”); *see also Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1471 (Fed. Cir. 1997) (“In order to render **a claimed apparatus** or method obvious, the prior art must enable one skilled in the art to make and use **the apparatus** or method.”) (citing *Beckman Instr., Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989)). Here, the claimed invention is “a **user-worn** device” capable of taking an “oxygen saturation” measurement. In short, if Lumidigm’s wristwatch could take a blood oxygen measurement **anywhere** on the body (it could), it would enable the claimed subject matter.

**Second**, the ID committed a further legal error by requiring more enabling disclosure from the prior art than the asserted patent itself provides. There is **no** disclosure, anywhere in the Poeze specification, of taking a blood oxygen measurement at the wrist. Instead, as discussed in section IV.A *supra*, **all** the disclosed embodiments are traditional **finger**-clip sensors for measuring **glucose**. JX-001 at 10:2-11:1 (“this disclosure is described primarily in the context of a finger measurement site”); 7:27-30 (“the present disclosure relates to an interface for a noninvasive glucose sensor”); 10:30-39, 10:62-11:2, 12:26-59, 15:21-23, 16:44-51, 30:3-9. The ID accordingly imposed an enablement standard on the prior art that the Poeze patents themselves would not meet, which was legal error. *See, e.g., In re Publicover*, 813 F. App’x at 532 (rejecting

argument that prior art was “too sparse to adequately explain to a skilled artisan” how to implement disputed limitation because the asserted patent was “just as sparse”); *In re Epstein*, 32 F.3d at 1568 (rejecting argument that prior art was not enabling where patent owner “did not provide the type of detail in his specification that he now argues is necessary in prior art references”); *In re Paulsen*, 30 F.3d at 1481 (rejecting argument that prior art was not enabling where “under the enablement standard that AST would have us apply to Yokoyama, the ’456 patent itself would be non-enabling. . . . If detailed disclosure regarding implementation of known electronic and mechanical components necessary to build a computer were essential for an anticipating reference, then the disclosure in the ’456 patent would also fail to satisfy the enablement requirement.”).

As the ID recognized, Lumidigm expressly discloses that its wristwatch can include “‘extended functionality’ including measurements of ‘**oxygenation** and/or hemoglobin levels in the blood.’” ID 114-15, citing RX-0411 at 17:64-18:2, 19:18-28. The ID found that this “extended functionality” is “**clearly applicable to the user-worn wristwatch**” and relied on it in finding that Lumidigm discloses and enables a user-worn device for measuring the “physiological parameter” recited in 502 claim 12. ID 92. However, the ID found that Lumidigm does not enable a wrist-worn device for measuring blood oxygen. *Id.* But under that standard, the asserted claims would themselves be invalid for failure to describe or enable their full scope. Simply put, if Lumidigm’s disclosure is not enabling of a wrist-worn device measuring blood oxygen (one “species” of user-worn devices measuring the same), the asserted claims of the Poeze patents themselves would be equally invalid for failure to describe or enable to full scope—that is, under the ID’s own logic, the claims would fail on written description and enablement grounds.

**Third**, even if enablement of a measurement at a wrist were required (it is not) and even if the ID could properly require more from Lumidigm’s disclosure than from the Poeze patents’



disclosure (it cannot), the ID still clearly erred in finding that a POSITA would not have understood how to take a blood oxygen measurement, including at the wrist, from Lumidigm's disclosure. Given Lumidigm's express disclosure of a wrist-worn device for taking an oxygen saturation measurement, there is a **presumption** of enablement. *See Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008) (“[A]n accused infringer ... enjoys a presumption that the anticipating disclosure also enables the claimed invention.”). Complainants bore the burden of overcoming this presumption with “persuasive evidence.” *See id.* The ID clearly erred in finding they did so. ID 115.

Apple's expert Professor Warren confirmed that oxygen saturation measurements were a “standard reflectance mode sensor application” long before the Poeze patents<sup>8</sup> and that a POSITA “would not have needed any additional information to make [pulse oximetry functionality] work” in Lumidigm's watch embodiment because this functionality was well understood at the time. Tr. 1216:10-25. Masimo's own expert, Dr. Madisetti, provided **no** testimony to the contrary. Although he characterized Lumidigm's disclosure as “vague and aspirational” (1330:20-1331:11), he provided no opinion on lack of enablement. The expert record thus stands **unrebutted** that a POSITA would have understood how to take a blood oxygen measurement with a wrist-based device. Indeed, for the reasons referenced above, if more disclosure were required to enable a POSITA to take a measurement on the wrist, the Poeze patents would themselves fail the test. *See In re Epstein*, 32 F.3d at 1568 (holding lack of disclosure in asserted patent regarding particular limitations supported finding that a POSITA “would have known how to implement the features” without explicit teachings and that the prior art was thus enabling).

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<sup>8</sup> The Poeze specification similarly confirms that using pulse oximeters to take oxygen saturation measurements was the “standard of care” before the Poeze Patents. JX-001 [’501 patent] 2:15-29.

Significantly, Dr. Warren further confirmed that his own *undergraduate* students were building pulse oximeters and taking oxygen saturation measurements—including *at the wrist*—by 2002, more than six years before the Poeze priority date:

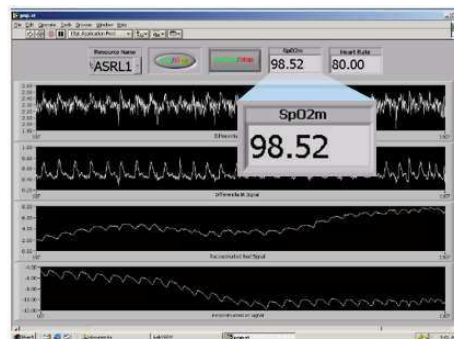
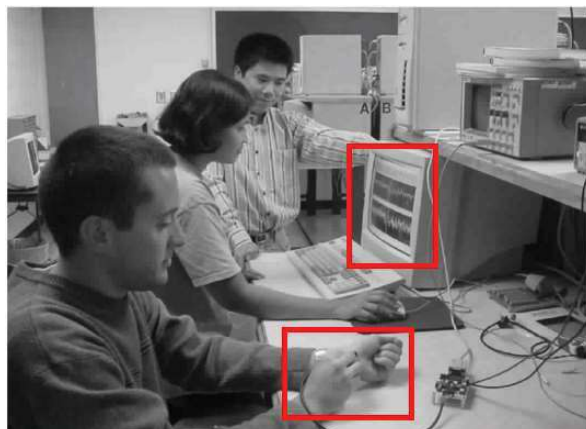


Figure 4. LabVIEW virtual instrument for the pulse oximeter. In addition to heart rate and blood oxygen saturation (%), the interface displays the red and infrared derivative data (top two waveforms) and the red and infrared reconstructed data (bottom two waveforms).

RX-0632 [2002 photograph] (annotated); RX-0508 [2005 paper] (annotated); Tr. [Warren] 1195:24-1196:10, 1216:10-25, 11:96:8-10 (“Q. Is that [a student] on the left taking a measurement from his wrist? A. It is, yes.”). The ID improperly dismissed this evidence because Dr. Warren “provided no testimony regarding the results of those measurements.” (ID 117.) But multiple corroborating documents, all published before the Poeze patents’ priority date, explicitly corroborated Dr. Warren’s testimony that a POSITA would have understood how to take a blood oxygen measurement at the wrist and that his students were doing so. *See, e.g.*, RX-0504.0001 [2005 student poster identifying the “[w]rist” as a “[v]iable and [u]nobtrusive [m]easuring [s]ite[.]” for pulse oximeters); RX-0508.0007 [2005 student article identifying the “wrist” as location for acquiring pulse oximetry signals]; RX-00335.001 at abstract, Fig. 3, 3:11-20, cl. 29 [patent, filed in 1996, describing oximetry probe for measuring “oxygen saturation” at locations including “wrist”].

The ID premised its finding primarily on testimony from Apple engineers concerning the challenges they faced in developing Apple Watch. ID 115-16. None of the cited testimony,

however, suggests measuring blood oxygen at the wrist was impossible at the time of the Poeze patents, or speaks at all to the disclosures of Lumidigm. Instead, as all these witnesses confirmed, while the wrist does differ from other parts of the body, the challenges they faced in developing Apple’s blood oxygen feature did not relate to the fundamental elements of pulse oximetry (which the Poeze patents attempt to claim), but instead related to adding that known functionality into the limited space of a small consumer device—while accounting for other considerations such as limited battery power, interference from other features, internal shipping deadlines, and Apple’s exacting industrial design standards that prioritized visual appearance. *See* Tr. [Warren] 1217:11-21, 1243:5-16; Tr. [Land] 963:19-964:25, 971:14-972:8; Tr. [Venugopal] 832:20-833:10; Tr. [Mehra] 853:22-854:855:3, 877:23-878:16; Tr. [Block] 902:13-903:2; Tr. [Waydo] 923:24-924:16, 925:23-926:6, 938:21-24; Tr. [Mannheimer] 998:15-999:11; Tr. [Kiani] 114:20-22. It was Apple’s need to ensure the feature would work across diverse populations and environments that took time to solve, not the underlying application of pulse oximetry.<sup>9</sup>

Finally, the ID also cited the testimony of one of Lumidigm’s inventors that he never personally built a wrist-worn device that calculated blood oxygen. ID 115. But it is textbook law that a patent can enable an invention even when there is no actual product. *See, e.g., In re Antor Media Corp.*, 689 F.3d 1282, 1290 (Fed. Cir. 2012) (“[O]ur precedent hold[s] that the invention in a prior art publication need not have actually been made or performed to satisfy enablement.”).

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<sup>9</sup> For the same reasons, the testimony of the Apple engineers does not support the secondary consideration of skepticism of the claimed invention and the testimony and evidence presented by Dr. Warren weighs against it.

**3. The ID Erred In Finding That Lumidigm, Alone And In Combination With Cramer, Does Not Disclose “Separate Openings Extending Through The Protrusion.”**

The asserted ’648 claims also require that the user-worn device include four photodiodes, with “separate openings extending through the protrusion” that are “positioned over” the photodiodes.<sup>10</sup> Apple explained that the “separate openings” would have been obvious based on Lumidigm alone (RIB 103) or combined with Cramer (RIB 108-109). The ID again committed further legal error in rejecting both arguments.

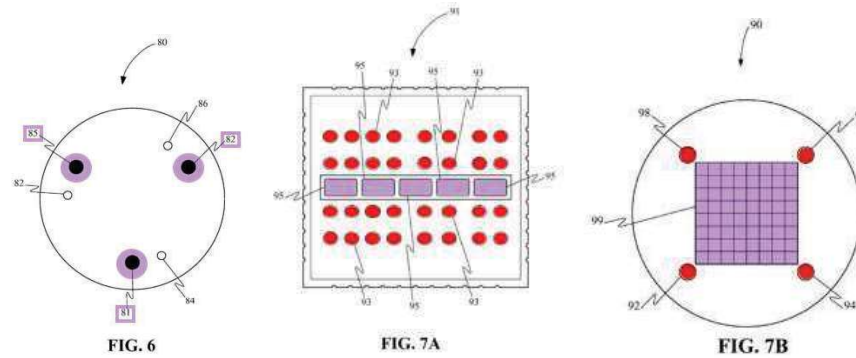
**a. Lumidigm Teaches The Openings.**

The ID improperly limited its analysis of Apple’s single reference obviousness argument to two figures in Lumidigm (Figures 7A and 7B), dismissed it based on an argument that Complainants and their expert did *not* make (that the “array-type” photodiodes shown in these figures could be formed with only a single opening<sup>11</sup>), and relegated Apple’s larger argument to a footnote. ID 120. But Apple’s obviousness argument—and the disclosures in Lumidigm on which it is based—was not so limited. Lumidigm emphasizes that its sensor can include *any* number of detectors – in *any* arrangement. RX-0411 at 6:54-63, 9:12-45, 9:52-57. Lumidigm illustrates such arrangements in its figures but states that “other numbers and arrangements” of sources and *detectors* (in purple below) “may alternatively be used” and that “[m]any variants exist”:

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<sup>10</sup> The asserted claims of the ’502 patent include the same limitations. The ID erred in its obviousness analysis of those claims for the same reasons as stated herein.

<sup>11</sup> Complainants did not dispute that Lumidigm discloses the claimed “openings” in its pre- or post-trial briefs. The pre-hearing brief did not raise this issue at all. The post-hearing brief argued only that, because Lumidigm does not disclose or suggest a “protrusion with a convex surface,” it also does not disclose openings in such a surface. CIB at 138. Complainants’ expert referenced these limitations vaguely, but never stated that Lumidigm’s Figure 7A and 7B embodiments, or any of its other embodiments, would have only a single opening. Tr. 1329-30, 1342.



*Id.* at Figs. 3-7B, 9:12-45. Lumidigm further explains that, for any of the “reflectance” type sensor heads shown in its figures, reflected light on the top surface of the tissue can be “detrimental” to optical measurements. *Id.* at 7:64-8:1. The detectors should thus be “recessed from the sensor surface” in “optically opaque material” to “minimize[] the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue” and to provide “optical blocking.” RX-0411 at 8:1-10. Lumidigm shows an example of such an opening in Figure 2:

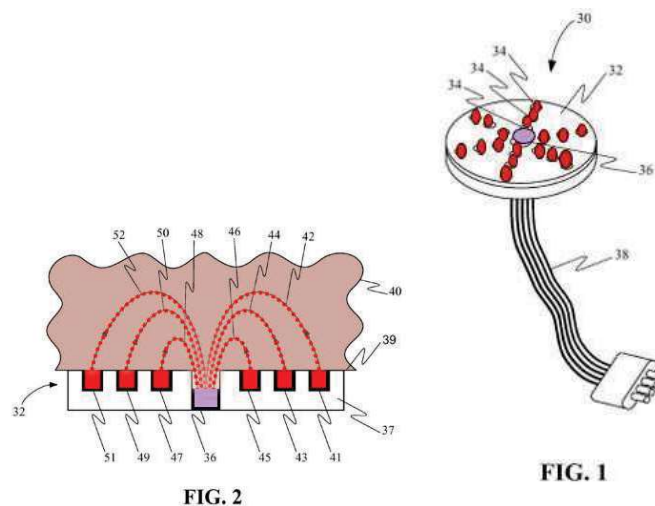


Figure 2 is a cross-sectional view of Figure 1, and shows Figure 1’s single detector (36) with an opening above it. RX-0411 at 7:5-6. As Dr. Warren explained, a POSITA would have understood that, for the embodiments with multiple photodiodes, the protrusion would include separate openings positioned over each of the photodiode: RX-0411 at Fig. 6-7, 6:54-56, 3:9-11; Tr.



[Warren] 1211:9-1212:10; RDX-8.28. The concept of including individual openings over each photodiode was a “quite well-known” idea, dating back to the “*late 60s*,” to allow light that has passed through the tissue to reach the detectors and to provide optical blocking of unwanted light. Tr. [Warren] 1211:10-12:12-3, *see also* 1192:25-1193:6, 1195:16-19.

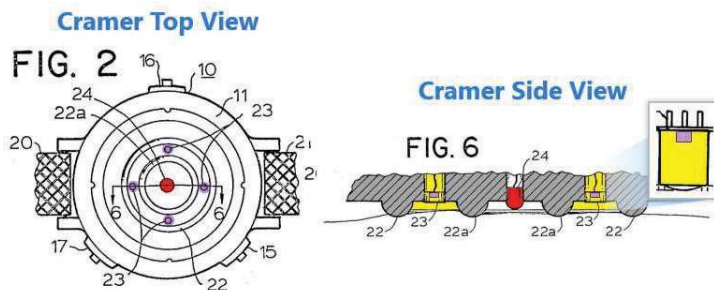
The ID erroneously dismissed Apple’s argument based on its conclusion that a POSITA *could* have used a single opening over four or more photodiodes in the array arrangements in Figure 7A and 7B. But it ignored that a POSITA *would* have used individual openings for any number of four-plus detector arrangements where the photodiodes are not in an array. The ID reached this conclusion by improperly limiting its analysis to the photodiode arrangements shown in Figures 7A and 7B—despite acknowledging that Apple identified those figures as merely “illustrative” examples of sensor arrangements including four photodiodes. But is black letter law that the prior art must be considered *as a whole*. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1076 (Fed. Cir. 2015) (holding district court’s dismissal of disclosure in prior art “violates the principle that [a] reference must be considered *for everything it teaches*” (internal quotation marks omitted)); *Raytheon Co. v. Sony Corp.*, 727 Fed. Appx. 662, 667 (Fed. Cir. 2018) (“[T]he combined teachings of the prior art *as a whole* must be considered.”); *Standard Mfg. Co. v. U.S.*, 25 Cl. Ct. at 53 (“Of particular importance is that each patent, including *each prior art reference, must be evaluated as a whole*.” (citing *Schenck v. Nortron Corp.*, 713 F.2d 782, 785 (1983))).

This error of law leads to a nonsensical result. The ID found—correctly—that in connection with ’501 claim 12, reciting a protrusion with “a *plurality of openings* extending through the protrusion and positioned over *three* photodiodes,” a POSITA “would have reason to modify the optical surface 39 of Lumidigm to form a ‘protrusion comprising a convex surface’ *and* that the modified optical surface “would extend over the photodiodes and the openings over them.” ID

106. If POSITAs would have been motivated to include a plurality of openings through the protrusion over three photodiodes (they would have), they would have been equally motivated to include separate openings through the protrusion over each of four photodiodes, particularly given Lumidigm's teachings that its sensor can include any number and any arrangement of photodiodes, its teachings that there should be openings over the photodiodes, and the broader knowledge in the art. RX-0411 at 6:54-63, 9:39-45, 9:52-57.

**b. Lumidigm And Cramer Also Teach The Openings.**

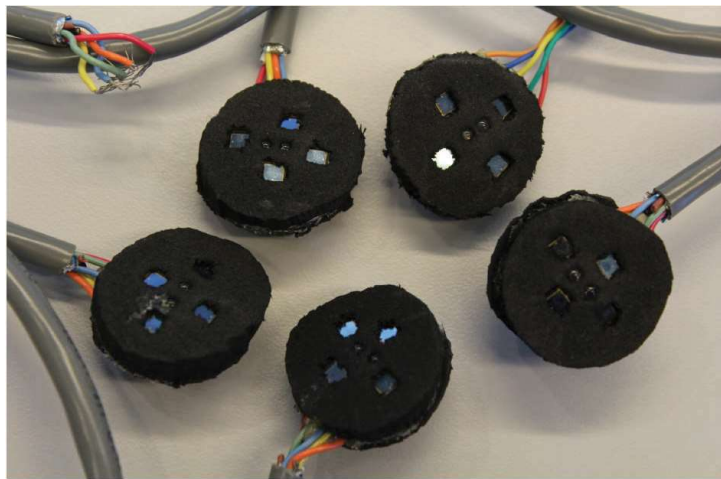
The ID also erred by summarily dismissing the combination of Lumidigm with Cramer, another wrist-worn physiological sensor, by applying the wrong legal standard to the combination and failing to consider the substantial evidence of a motivation to combine. Cramer discloses the exact arrangement recited in the claims – with *four photodiodes* (in purple below) arranged in a quadrant and “*separate openings*” (in yellow below) for each of the photodiodes:



RX-0670 at Figs. 2, 6 (annotated including with excerpt from RX-1221).<sup>12</sup> As Dr. Warren explained, Lumidigm expressly invites the combination with Cramer through its teachings that its

<sup>12</sup> Cramer's sensor includes four photodiodes and a sensor head or "boss region" with separate openings positioned and arranged over each of the four photodiodes. RX-0670 at 5:12-62, Figs. 2, 3, 6. Cramer states that a "suitable detector" for its embodiments is the Clairex "CLT 2160 photo diode." *Id.* at 5:33-35; RX-1221 at 1; Tr. [Warren] 1193:24-1194:14. Cramer describes and its figures show four of the CLT 2160 detectors arranged in a quadrant with separate openings over each of the photodiodes. *Id.* at Figs. 2, 3, 6. As Dr. Warren confirmed, a POSITA would recognize the CLT 2160 as a "can" detector and would understand that each can would be made from an opaque material, that the can would include a lens at the end of the can near the tissue

sensor can include any number and any arrangement of photodiodes and that there should be openings over each of the photodiodes, made with opaque materials, to allow light to pass while providing optical blocking of unwanted light and avoiding light shunting. RX-0411 at Fig. 3-7B, 9:30-45, 7:64-8:11. Again, the use of separate openings, positioned over photodiodes, was “well-known” in the art by the time the Poeze patents were filed, dating back to the “*late 60s*,” and taught in many of the prior art references Dr. Warren discussed. Tr. [Warren] 1192:25-1193:6, 1195:16-19, 1211:10-1212:3. In fact, Dr. Warren’s own *undergraduate* students, once again, built sensors with four photodiodes, with “separate openings extending through the protrusion” and “positioned over” each of the photodiodes, many years before the Poeze priority date:



surface, and that there would be a gap between the detector and the lens, creating separate openings between the detector and the lens positioned over each of the photodiodes. RX-0670 at Fig. 6; RX-1221 at 1; Tr. [Warren] 1231:23-1232:9, 1234:3-8; RDX-8.70 (summarizing RX-0666, RX-0670, RX-1221). This understanding is consistent with Cramer’s disclosures and figures, as well as the data sheet for the CLT 2160 referenced in Cramer’s specification. RX-0670 at 5:33-35, Fig. 6; RX-1221 [CLT 2160 Data Sheet] 1.

Cramer also discloses light blocking rings that create a second layer of opaque lateral surfaces relative to each of the photodiodes. RX-0670 at 2:46-51, 5:45-51, Fig. 6. Cramer’s canned photodiodes provide separate openings in the protrusion with “another layer” of opaque surfaces around each of the openings. Tr. [Warren] 1234:3-8; *see also* RX-1221; Tr. [Warren] 1231:15-1232:9, 1233:15-1234:8; RDX-8.70-RDX-871.

RX-0519 [2002 photo]; RDX-8.88 [2002 photos including RX-0519]; Tr. [Warren] 1195:23-1196:16. A POSITA would have been motivated to combine Lumidigm with Cramer because Lumidigm expressly teaches the benefits of separate openings over each of the photodiodes and, more generally, because the benefits were well known. Tr. [Warren] 1233:15-1234:21.

Despite this wealth of evidence supporting the combination, the ID rejected this combination in a short, conclusory paragraph, stating that “the evidence does not clearly and convincingly show that one of skill in the art would have a reason to combine the *specific structures* of Cramer with Lumidigm” and that “Cramer only includes one LED.” ID 121. This finding applied the wrong legal standard. As the Federal Circuit has repeatedly confirmed, including *en banc*, the relevant issue is not whether there would have been motivation to combine *the specific structures* of the prior art, but rather, whether the claimed invention is obvious based on the “teachings of the prior art *as a whole*.” *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (*en banc*) (“Etter’s assertions that Azure cannot be incorporated in Ambrosio are basically irrelevant, the criterion being not whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole.”); *see also Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (quoting *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) (“it is not necessary that [the prior art] be physically combinable to render [a claim] obvious.”)); *In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (“It is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements.”).

**C. The Commission Should Grant Review Of The “Technical Prong.”**

Complainants’ rush to file its Complaint also led to fatal flaws in its domestic industry case. While the ID correctly adhered to Commission precedent in holding that a domestic industry must

be evaluated as of the time of the Complaint, it erred as a matter of law when it found that Complainants satisfied the technical prong for an existing domestic industry as of that time. While Complainants identified the “Masimo W1” as the domestic industry for the Poeze patents, they produced no direct evidence that the actual devices they relied on practiced claim 12 of the ’501 patent; claim 28 of the ’502 patent; and claims 12, 24, and 30 of the ’648 patent as of the time of the Complaint.<sup>13</sup> To the contrary, the evidence confirms most of those asserted articles did not even exist at the time. Absent such evidence, the ID committed legal error by relying on what it characterized as “circumstantial evidence” related to *other* prototypes that are not the proffered DI articles to find the technical prong satisfied. The ID further erred in its alternative finding that the technical prong was satisfied for an “in progress” domestic industry “even if” Complainants failed to identify any practicing article.

**1. The ID Erred In Relying On “Circumstantial Evidence” Not Linked To The Actual Asserted DI Articles To Find The Technical Prong Satisfied For An Existing Domestic Industry.**

The ID acknowledged that an existing domestic industry requires an actual physical article that practices each limitation of the asserted claim. ID 82 (citing *Microsoft Corp. v. ITC*, 731 F.3d 1354 (Fed. Cir. 2013)). The *Microsoft* court held that the language of Section 337(a)(2) and (3), referring to “articles protected by the patent,” requires that “[a] company seeking section 337 protection must . . . provide *evidence that . . . relates to an actual article* that practices the patent.” *Id.* at 1362. In that case, complainant Microsoft’s evidence was insufficient to establish a domestic industry because Microsoft relied on source code that was not the “specific code actually installed and run on a particular third-party mobile device.” *Microsoft*, 731 F.3d at 1362. Here, the ID

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<sup>13</sup> Complainants have not argued that any article satisfies the technical prong for claim 22 of the ’502 patent. See ID 55-56; CIB 102-112 (discussing only claim 28 of the ’502 patent with respect to domestic industry).

erred in relying on what it characterized as “circumstantial evidence” similarly *not related* to the *actual devices* proffered by Complainants to find the technical prong satisfied.

**a. The ID Erred In Considering Devices That Post-Date The Complaint.**

While the ID (at 59) correctly held that “post-complaint evidence regarding the alleged domestic industry will not be considered,” it clearly erred in applying this standard to the facts. Complainants relied on six different physical devices in their attempt to satisfy the technical prong for the Poeze patents: The RevA sensor (*CPX-0052C*), the RevD sensor (*CPX-0058C*), the RevE sensors (*CPX-0019C*, *CPX-0020C*, *CPX-0065C*), and the Masimo W1 (*CPX-0146C*). *See* ID 55. The ID rightly did “not consider any evidence regarding the Masimo W1 product [*CPX-0146C*], because this product was made ... several months after the complaint was filed.” ID 59. However, it incorrectly considered all five of the remaining prototype devices notwithstanding that all but the RevA device (*CPX-0052C*) were also created or altered *after* the Complaint was filed:

- Masimo’s Director of Sensor Design Stephen Scruggs testified that the software on the RevD sensor (*CPX-0058C*, which has [REDACTED] did not *exist* until July 30, 2021—well after filing of the Complaint.<sup>14</sup> Tr. [Scruggs] 459:4-460:7; Tr. [Sarrafzadeh] 1121:9-24; RX-1183C.0035.
- Mr. Scruggs testified unequivocally that one of the RevE sensors (*CPX-0020C*) “was created in *September* of 2021”—months after the Complaint was filed. Tr. [Scruggs] 458:1-459:2.
- Mr. Scruggs could not specifically identify a date when the other two RevE sensors (*CPX-0019C* and *CPX-0065C*) were made, other than that it was sometime “‘*between* May and *September of 2021*.’” Tr. [Scruggs] 398:20-23.

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<sup>14</sup> Mr. Scruggs also confirmed that without software, the prototype devices are not operational. Tr. [Scruggs] 460:8-12. Complainants offered no evidence regarding any other software version allegedly loaded on *CPX-0058C* prior to July 30, 2021.

- Each of CPX-0019C and CPX-065C was altered after the filing of the complaint at least to change software versions. ID 84, n.23; RX-1183C.0037-0039.<sup>15</sup>

Given this undisputed evidence, it was error to consider any of the RevD and E prototypes (CPX-0058C, CPX-0019C, CPX-0020C, or CPX-0065C) in evaluating Complainants' domestic industry allegations. To do so, the ID concluded not that these *devices* existed at the time of the Complaint but rather that "circumstantial evidence" showed that *other*, unspecified "prototype devices with designs that are *consistent with* the asserted domestic industry products were operational before the filing of the complaint." ID 83-84, n.22; *see also id.* at 84-85 (relying on evidence of testing of devices but "not the specific devices produced"). As discussed further below, it was legal error to rely on this testing evidence precisely because it does not relate to the actual asserted DI articles. Nor is there any evidence to support the ID's apparent assumption that all prototype devices with an allegedly similar sensor design necessarily operate the same or are identical in all relevant respects. Were that so, there would have been no reason for Complainants to assert three separate "RevE" devices as they did.

**b. The ID Erred In Relying On Testing Evidence Not Related to the Actual Asserted DI Articles To Conclude They Were "Configured To ... Measure Physiological Parameters."**

The ID similarly erred by relying on evidence of testing of *other* prototypes—*i.e.*, not the actual asserted DI articles—to conclude the actual asserted DI articles were each configured to

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<sup>15</sup> While Complainants represented that the software version on these articles as of the hearing existed as of July 9, 2021 and was "[f]irst loaded and operated on [these] physicals on *approximately* July 9, 2021," this is not sufficient to carry Complainants' burden with respect to these devices as it fails to provide an exact date. RX-1183C.0037-0039. Moreover, as the ID acknowledged (84, n.23), Complainants first filed their amended Complaint on *July 7, 2021*. The confidential version was inadvertently filed publicly, which Apple informed Complainants of. Complainants then refiled the full confidential version on July 12, 2021. Complainants should not be permitted to reap the benefits of their own filing error by now relying on devices that post-date July 7, 2021.



[REDACTED]

measure physiological parameters as required by '648 claim limitations;<sup>16</sup> [8pre]; [8G]; [12]; [20pre]; [20E]. The ID concluded that “Complainants have shown ... that the RevA, RevD, and RevE devices measure blood oxygen saturation” based on testimony from Complainants’ employee Mr. Al-Ali describing “testing of blood oxygen functionality conducted in 2020 using prototype designs *consistent with the RevA sensor*, additional testing *in the timeframe of the RevD devices* in early 2021, and further testing *of RevE devices in June 2021.*” ID 61. Nothing in the record connects this generic testimony or evidence of *other* devices “consistent with” or within the “RevA,” “RevD,” and “Rev E” categories to the actual devices Complainants relied on.

With respect to the sole RevA sensor (CPX-0052C), the only device arguably shown to even exist in its current form when the Complaint was filed, the ID relied on a [REDACTED] (CX-0378C) admittedly *not* of the RevA sensor itself but of another “sensor *with a design consistent with the RevA device.*” ID 60-62 & n.16. But Complainants did not introduce any testimony or other evidence to establish that all sensors with designs “consistent” with CPX-0052C would perform similarly or all be configured to measure physiological parameters. To the contrary, Complainants identified numerous “RevA” devices during discovery, yet identified only one as allegedly practicing the asserted claims at the hearing and [REDACTED]

[REDACTED] See RX-1183C at App’x 82.A.2 (identifying CPX-0017C, CPX-0051C, CPX-0053C, CPX-0055C and CPX-0057C as “RevA”); RX-1183C.0015 (identifying CPX-0053C and

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<sup>16</sup> to the same requirements exist in '501 patent limitations [1pre], [1F] and '502 patent limitations [28pre]; [28I]. To the extent the Commission finds these limitations not met for the '648 patent the technical prong is not satisfied for any Poeze patent. Complainants did not allege that the “RevA” device CPX-0052C practiced claim 28 of the '502 Patent. ID 69 n.20.

CPX-0055C (MASITC\_P\_53 and MASITC\_P\_55) [REDACTED]

[REDACTED]; *see* Complainants Pre-Hearing Statement, Ex. E at Physical Exhibit List.<sup>17</sup>

There is similarly no evidence of any testing of the sole RevD device (CPX-0058C) or of the three RevE devices (CPX-0019C, CPX-0020C, and CPX-0065C) before the Complaint. While the ID relied upon CX-0494C as testing “of Rev E devices” generally (ID 60), none of the pre-Complaint testing in that document relates to the actual RevE articles relied on by Complainants, which, as discussed above, did not exist in their current form until after the Complaint was filed. *Compare* CX-0494C pp. 1-38 (identifying prototypes tested before the Complaint: P1005, P1007, P1014, P1015, P1013, P1019) *with* RX-1183C.0018-23 (providing “identifier” for CPX-0019C (00014); CPX-0020C (0000000016) CPX-0065C (P1008)); *see also* Tr. [Al-Ali] 316:2-317:13.<sup>18</sup> Absent evidence directly related to the asserted DI articles, the ID credited the same [REDACTED] [REDACTED] discussed above as “strong circumstantial evidence” that *all* asserted DI articles were capable of measuring blood oxygen. ID 62, n.16. But this alleged [REDACTED] does not show testing results from any device offered in this Investigation. The study was conducted before October 6, 2020 (CX-0378C, *see also* Tr. [Al-Ali] 270:1-16)—while the RevA sensor (CPX-0052C) was “built in November of 2020” (Tr. [Scruggs] 396:2-11); the RevD sensor (CPX-0058C) was “made in April of 2021” (Tr. [Scruggs] 397:23-24) and the relevant RevE sensors (CPX-0019C, CPX-0020C, and CPX-0065C) were built sometime “between May and September of

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<sup>17</sup> Moreover, at the hearing, Mr. Al-Ali described devices that he alleged were developed contemporaneously (late 2020) with CPX-0052C but that differed in design—such as the curvature of the back—in a way that could affect the ability to take measurements. Tr. [Al-Ali] 265:15-268:1.

<sup>18</sup> While CX-0494C depicts test results from one actual asserted DI article, CPX-0065C, this testing occurred *after* the filing of the Complaint. CX-0494C at, *e.g.*, p. 57 (testing on July 19, 2021); RX-1183C.0022. As discussed above, the evidence does not show that CPX-0065C existed at the time of the Complaint. Thus, this testing should be disregarded pursuant to the ID’s correct holding that “Complainants’ post-complaint activities will not be considered.” ID 57.

2021.” Tr. [Scruggs] 398:20-23. That Complainants may have been capable of creating *some* sensor capable of measuring blood oxygen at some earlier time does not relieve them of their burden to show that the asserted DI articles practice all elements of the asserted claims.

If only evidence related to the *actual* asserted DI articles is considered, Complainants failed to meet their burden to show by a preponderance of the evidence that any of those devices was configured to measure physiological parameters as of the time of the Complaint. As the ID acknowledges, the only evidence specific to the asserted DI articles came from experts.

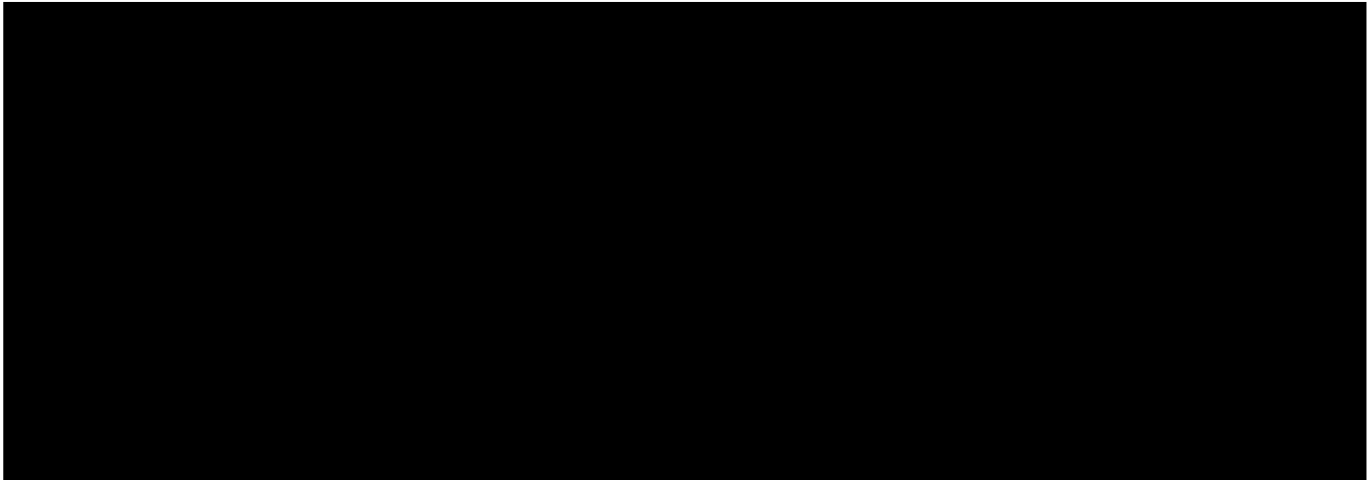
Complainants’ expert Dr. Madisetti offered nothing more than conclusory testimony that “as described ... in this slide,” the devices themselves “confirm that it’s a user-worn device that can be configured to non-invasively measure a physiological parameter.” Tr. [Madisetti] 710:23-711:10. But Dr. Madisetti’s slide showed nothing other than a graphic of a “Masimo W1” and images of the underside of the asserted DI articles. CDX-0011C.0048. With respect to ’501 patent claim limitation [1F]—which requires processors configured to measure physiological parameters—Dr. Madisetti’s declaration that the devices “calculate oxygen saturation” was similarly without explanation. Tr. [Madisetti] 715:20-716:21.<sup>19</sup> While Dr. Madisetti testified that Mr. Scruggs demonstrated for him “Rev A, D, E and Masimo W1 Watches,” he did not explain how that observation supported his conclusion. Tr. [Madisetti] 716:8-21. To the contrary, Dr. Madisetti admitted he did not see *any* of the actual asserted DI articles in person before forming his opinions; did not record results of the demonstrations he observed; and failed to compare the results of those demonstrations to a reference device. Tr. [Madisetti] 800:2-801:5, 802:3-7,

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<sup>19</sup> Dr. Madisetti did not offer any additional evidence on the comparable limitations in the asserted claims of the ’502 and ’648 patents, but only incorporated by reference his analysis for ’501 patent limitation [1F]. Tr. [Madisetti] 720:14-20; 724:21-725:18; CDX-0011C.0058, CDX-0011C.0064-65.

802:14-22. Further, although the burden is Complainants', Dr. Madisetti did not demonstrate even one of the asserted DI devices at the hearing, nor did Dr. Madisetti (or Complainants) introduce *any* source code showing how any of the asserted DI articles satisfies these limitations.<sup>20</sup>

Apple's experts Drs. Sarrafzadeh and Warren, on the other hand, testified and introduced the results of their observation of *the actual asserted DI articles*:



RDX-0007C.154 (citing RX-0259C – RX-0260C; RX-0262C – RX-0270C); *see also* RX-1470; Tr. [Warren] 1257:1-19; RDX-0008C.0147 (citing RX-0265C – RX-0270C).

Both Drs. Sarrafzadeh and Warren concurred that these results do not show that the asserted DI articles are configured to measure physiological parameters. Tr. [Sarrafzadeh] 1122:7-1124:23; Tr. [Warren] 1254:8-1256:25 (“My opinion is that these DI articles do not implement the functionality [] that’s in the claims, because I was not able to establish that they were producing physiological parameters ... Q. ... Has Masimo established that its DI devices meet these

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<sup>20</sup> Apple's experts also explained that [REDACTED]  
[REDACTED]  
[REDACTED] Tr. [Sarrafzadeh] 1124:24-  
1125:11; 1126:22-1127:7; Tr. [Warren] 1257:20-1258:8 (similarly explaining the [REDACTED]  
[REDACTED]  
[REDACTED] RX-1397C.

[REDACTED]  
[REDACTED]  
[REDACTED]

limitations [requir[ing] a noninvasive measurement of the physiological parameter]? A. I have not been provided with enough evidence to confirm that, *so my opinion is no.*”); *id.* at 1258:9-17.

Although Complainants [REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] Drs. Sarrafzadeh and Warren testified the data observed was insufficient to show measurement of physiological parameters. Tr. [Sarrafzadeh] 1123:3-1124:24; Tr. [Warren] 1254:11-24; *see also* Tr. [Scruggs] 446:3-7.

The pulse rate readings on the RevA device (CPX-0052C) alone—the only device that arguably existed before the Complaint as Complainants rely on it—[REDACTED], while pulse rate readings for the other devices were [REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] Tr. [Warren] 1254:25-1256:1; Tr. [Scruggs] 446:24-448:1; Tr. [Scruggs] 419:8-14; *see also* Tr. [Warren] 1255:6-11 (describing the pulse rate measurements as all “too high or too low”). Similarly, the vast majority of the readings allegedly for blood oxygen saturation across CPX-0052C, CPX-0058C, CPX-0019C, CPX-0020C and CPX-0065C were [REDACTED] but as Professor Warren explained (and Mr. Scruggs confirmed), [REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] Tr. [Warren] 1255:6-1256:1; Tr. [Scruggs] 449:13-450:9 [REDACTED]  
[REDACTED]); RX-1470C.

When properly limited to evidence related to the *actual devices* Complainants alleged practice the Poeze patents, Complainants have not met their burden to show any was configured to measure a physiological parameter at the time of the Complaint.

**c. The ID Erred In Relying On The Unrelated Testing Evidence To Find That CPX-0052C And CPX-0058C Are “User-Worn.”**

The ID also again erred in relying upon the testing evidence discussed above to show that the RevA prototype (CPX-0052C) and one of the RevE prototypes (CPX-0058C) were “user-worn” devices or contained a strap as required by limitations [8pre], [8I] and [20pre] of the ’648 patent.<sup>21</sup> It was undisputed that neither article actually has a strap in its current form that would allow it to be worn by a user:



*See also* ID 63

*see also* Tr. [Scruggs] 460:13-22

*id.* 463:23-464:3 (same for CPX-0052C); CPX-0052aC and CPX-0058aC.

The ID concluded that CPX-0052C and CPX-0058C are “user worn device[s]” in part because they have “attachment mechanisms for a strap, and Mr. Scruggs testified that these devices had straps ‘at one point in time.’” ID 63 (citing Tr. [Scruggs] 405:8-406:3, 406:23-407:18, 460:13-

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<sup>21</sup> Similar limitations are present in ’501 patent limitations [1pre], [1F] and ’502 patent limitations [28pre]; [28I]. To the extent the Commission finds these limitations not met for the ’648 patent, the technical prong is not satisfied for any Poeze patent.

17). But Mr. Scruggs did not testify regarding *when* these devices allegedly had straps—i.e., whether it was before the Complaint. To conclude as much, the ID relied again on Mr. Al-Ali’s testimony and testing evidence of *other* prototypes that “suggests the devices were ‘user-worn.’” ID 63 & n.19. However, as shown in Section IV.C.1.b, *supra*, the testing discussed by Mr. Al-Ali does not relate to CPX-0052C and CPX-0058C specifically. Thus, it was error for the ID to rely on this flawed “circumstantial evidence” to find that these devices were “user-worn” or had a strap at the relevant time. ID 63; 83.

**d. The ID Erred By Relying On Technical Documents Not Representative Of The Actual DI Articles To Find Other Limitations Met.**

The ID erred by concluding the asserted DI articles had the components to satisfy Elements [1B] and [1E] of the ’501 patent, [28A] through [28D] of the ’502 patent, and [8A], [8C], [20B], and [24] in the ’648 patent based upon CAD files not tied to the actual articles. ID 64-67, 69-71, 75-76, 79-80, 81. Complainants’ expert replied upon these files as evidence that these limitations were met. *Id.* However, as the ID recognized based on Mr. Scruggs’ testimony, none of these CAD files accurately depicts the actual asserted DI articles. ID 64 (“Mr. Scruggs admitted that there were certain discrepancies between Masimo’s CAD files and the actual RevA, RevD, and RevE sensors, recognizing that the devices represented ‘what we were able to manufacture at the time.’” (quoting RX-1209C (Scruggs Dep.) at 91:18-92:24); *see also* Tr. [Scruggs] 465:2-467:18 (confirming “there are some differences” between the CAD files and each asserted DI device).

Despite the CAD files admittedly not accurately reflecting the design of the actual asserted DI articles, the ID nevertheless relied upon them based solely on Mr. Scruggs’ testimony that “‘the essential meat and potatoes stuff, like the sensor, it’s very accurately reflected’ by the CAD drawings, because ‘that’s very important for the devices.’” ID 65 (quoting Tr. [Scruggs] 467:2-7,



477:9-478:8). The ID's assumption that the so-called "meat and potatoes stuff" in the CAD files accurately reflected the relevant portions of the actual asserted DI articles is unsupported, and therefore insufficient to establish the technical prong.

As a preliminary matter, Mr. Scruggs never explained what device features correspond to the "meat and potatoes stuff" in the CAD files or what features fall outside of that description. This makes impossible to determine whether the CAD files accurately disclose any claim limitation. Moreover, Mr. Scruggs' "meat and potatoes" testimony was only specific to a *single* device, CPX-0019C. *See* Tr. [Scruggs] 467:2-7 ("Q. And as another example, there's differences between the design depicted in the CAD file and the actual design of CPX-19C, correct? A. Yes, there are differences between those physicals, but like the essential meat and potatoes stuff, like the sensor, it's very accurately reflected."). Mr. Scruggs offered no similar testimony with respect to *any* of the other devices. To the contrary, Mr. Scruggs confirmed that "there are some differences" between the CAD files and every single asserted DI device. Tr. [Scruggs] 467:8-18. But again, Mr. Scruggs never identified or described those differences, rendering the ID's assumption about their accuracy incorrect.

The ID similarly relied upon testimony from Mr. Al-Ali as "confirming the accuracy of the CAD drawings for the RevE sensors." ID 65 (citing Tr. [Al-Ali] 313:144-314:7). However, like the testing evidence he sponsored, Mr. Al-Ali's testimony appears to relate to a generic category of "RevE" sensors, not any particular device. Moreover, Mr. Al-Ali's testimony is directly contradicted by Mr. Scruggs' testimony confirming differences between the CAD files and each asserted DI article, including the three "RevE" devices. Tr. [Scruggs] 467:8-18. Conflicting testimony from Complainants' own witnesses cannot establish the technical prong.

Ultimately, it was error for the ID to assume that the CAD files met the burden of proof for the elements of the Poeze patents when Mr. Scruggs disavowed their accuracy. The inaccuracies of the CAD files mandates that they cannot be used to demonstrate the technical prong.

**2. The ID Erred In Its Alternative Finding Of Technical Prong For A Domestic Industry “In The Process” Of Being Established.**

The ID further erred in its alternative finding that the technical prong is satisfied for a domestic industry “in the process” of being established. In the decision relied on by the ID (at 85), *Certain Televisions, Remote Controls, and Components Thereof*, Inv. No. 337-TA-1263, Comm’n Op. at 24 (Nov. 30, 2022), the Commission declined to adopt a *per se* rule requiring an actual physical article in all cases, leaving open the theoretical possibility that practice of claim limitations could be shown based on a “likelihood” that a currently non-existent but nevertheless potential future product would practice the patent. Apple respectfully disagrees; the statutory language and the holding require a domestic industry “relating to the articles protected by the patent,” and demonstrating “articles protected by the patent” requires actual physical articles that practice the patent. *Microsoft*, 731 F.3d at 1362. In any event, in the 1263 Investigation the Commission found that the technical prong had **not** been satisfied, and the same finding should be made on the record in this Investigation. In the 1263 Investigation, the ALJ found that respondents had “no opportunity to evaluate” whether the complainant’s “future promised product would actually practice the claims” of the asserted patent. Inv. No. 337-TA-1263, Comm’n Op. at 25. The same is true here.

The ID in this Investigation held that, “even if” the evidence is insufficient to demonstrate that the identified prototypes existed at the time of the complaint, the “design documents and testing results” demonstrate that the “Masimo Watch prototypes in development” “would result in a product practicing the asserted claims.” ID 87 & n.27. However, Complainants’ proffered

evidence in discovery and at the hearing did not provide Apple with an “opportunity to evaluate” whether any anticipated future products would practice the asserted patents. As discussed above, the technical documents offered by Complainants were admittedly *not* representative of the actual articles asserted. *Supra* Section IV.C.1.d. The ID here could only find the technical prong satisfied by relying on “circumstantial evidence” not linked to specific prototype devices offered into evidence. *See supra* Section IV.C.1. Nor do any technical documents offered by Complainants accurately show the future “Masimo W1”—“the only Masimo watch ... that Masimo plans to commercialize.” RX-1209C (Scruggs Jan. 6 Dep.) 177:24-178:6. To the contrary, the ID properly did not consider evidence regarding the W1 because it post-dates the Complaint.

Ultimately, the ALJ’s final reasoning was backwards. She relied on her separate erroneous findings that the RevA, RevD, and RevE devices practiced the ’502 and ’648 patents, then backfilled with hindsight, relying on insufficient circumstantial evidence to find that prototypes to these devices which existed prior to the complaint also practiced these patents. *See Certain Video Game Sys. & Controllers*, Inv. No. 337-TA-743, Comm’n Op. (Pub. Version) at 5 (Jan. 20, 2012) (“the only activities that are relevant to the determination of whether a domestic industry exists or is in the process of being established are those that occurred before the complaint was filed.”). Just because Masimo’s prototypes went through an “iterative process” of design does not relieve it of its burden to prove exactly what its prototypes could practice at the time the complaint was filed. ID 87. When one looks at the circumstantial evidence on its own it is not sufficient to meet the Complainants burden to establish that a device that would practice the patents in the future. The Commission should therefore review of the ID’s domestic industry analysis and correct the errors as to the technical prong for Elements [1pre], [1B], [1D], [1E] and [1F] of the ’501 patent, [28pre],

[28A] through [28D], [28F], [28I] and [28M] of the '502 patent, and [8pre], [8A], [8C], [8E], [8G], [8I], [12], [20pre], [20B], [20D], [20E], [24] and [30] in the '648 patent.

**D. The Commission Should Grant Review On Non-Infringement.**

The ID committed further legal error in its infringement analysis, which applied flawed claim constructions and ignored the functional limitations of the Accused Apple Watches, which do not infringe under the plain meaning of the claims.

**1. The ID Erred in Finding The Accused Apple Watches Have A Protrusion And Openings “Over” And “Above” The Interior Surface And Photodiodes.**

The Accused Apple Watches do not infringe '648 claims 24 and 30 (or any of the other asserted Poeze claims) because they lack a protrusion arranged “*over*” or “*above*” the “interior surface” or “photodiodes” when the device is “configured to non-invasively measure” blood oxygen saturation (the accused physiological parameter) and its processors are “configured to” “calculate,” “output,” or “determine” such measurement. JX-001 at cl. 12; JX-002 at cl. 22, 28; JX-003 at cl. 24, 30. The ID’s finding that the Accused Apple Watches infringe relied on an incorrect claim construction that Complainants did not even advance before the hearing.<sup>22</sup> See ID 35, 41, 45. The ID found the terms “over” and “above” “do not require *a vertical arrangement*” and instead “refer[] to an arrangement where one feature *covers* another.” ID 29. The only support that the ID cited for this alleged plain meaning interpretation of “over” is extrinsic evidence—specifically, the ID credited the testimony of Complainants’ expert Dr. Madisetti to find that “‘over’ *can* be also be used to describe an arrangement where one features covers another, as recognized by Dr. Madisetti’s

<sup>22</sup> Complainants asserted (for the first time) in their initial post-hearing brief that “over” and “above” refer to “the configuration of features of the device relative to each other, not to the position of the device relative to the Earth.” CIB 43.

example of a bandage over the wound.”<sup>23</sup> *Id.* But nothing in the intrinsic evidence supports this meaning of “over.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (specification “is the single best guide” for claim construction). To the contrary, the *only* time the Poeze specification uses the positional “over” language with respect to the protrusion refers to a transmissive, finger-worn embodiment where the protrusion is positioned “over” (i.e., above) the interior surface as shown in Figure 6E. *See* RIB 28; JX-001 [’501 patent] 24:27-33, Fig. 6E. Indeed, in every embodiment depicted in the Poeze patents, the protrusion is spatially positioned on top of, or higher than, the photodiodes, consistent with the plain meaning of “above” and “over.” *See* Figs. 3C, 4C, 7B. Contrary to the ID’s error, “over” and “above” as used in the patents plainly refers to a vertical arrangement.<sup>24</sup> Under that correct construction, the Accused Apple Watches do not infringe because they *never* satisfy all limitations. RIB 26-34; *Engel Indus. v. Lockformer Co.*, 96 F.3d 1398, 1405 (Fed. Cir. 1996) (“Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device....”). Neither the ID nor Complainants disputed that Apple Watch *cannot* take a blood-oxygen measurement when face-down—i.e., in a configuration in which the protrusion and openings are “*over*” and “*above*” the interior surface housing the photodiodes. Apple’s engineers, algorithms, and product literature all confirm that, in order to measure a user’s average blood-oxygen saturation, Apple Watch cannot be face down

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<sup>23</sup> The fact that the ID recognized multiple plausible interpretations—i.e., “the word ‘over’ *may be used to describe a vertical arrangement*, but [] can also be used to describe an arrangement where one features covers another”—further suggests a more thorough analysis rooted in the principles of claim construction is warranted. *See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008) (“A determination that a claim term ... has the ‘plain and ordinary meaning’ may be inadequate when a term has more than one ‘ordinary’ meaning[.]”).

<sup>24</sup> The ID’s construction of “above” was similarly flawed. *See* ID 29, n. 4. Although the ID stated that “the patent *specification* does not require any specific orientation of the device and that *the term ‘above’ thus refers to a position relative to the device’s features*,” the ALJ did not root this finding in any intrinsic evidence. *Id.*

(i.e., in a configuration in which the protrusion is “above” or “over” the photodiodes and protrusion). *See* RIB 26-34; RRB 29-34; Tr. [Waydo] 926:23-927:9, 928:9-929:11, 930:18-931:14; Tr. [Warren] 1250:23-1252:6; RX-0307C.0004; CX-0010.3; RX-0812.0001; RX-0748; RX-0700; Tr. [Waydo] 919:1-8, 926:23-927:18; *see also* CX-0299C [Waydo Dep.] 169:20-172:10; CX-0281C [Block Dep.] 276:22-277:20, 107:18-109:12, 112:12-19, 113:17-114:4; Tr. [Venugopal] 847:20-23; CX-0289C [Mannheimer Dep.] 188:7-11; RX-0307C.0004 [REDACTED] [REDACTED] CX-0010.3; RX-0812.0001; RX-0748 (Series 6); RX-0700 (Series 7); RDX-8.142C (summarizing RX-0307C, RX-0748, RX-0700, RX-0812); *see also* JX-001 at 24:27-33; CX-0010.3; RDX-8.140C. Indeed, the only way the ID can reach its finding of infringement is to conclude that the dome on the back of the Accused Apple Watches is somehow “over” and “above” the face of Watch in ***both*** the following orientations:



Photographs of RPX-2; *see also* Tr. [Madisetti] 792:16-20 (confirming that under his interpretation of claims dome is “over” the interior photodiodes in both orientations above).

Even under the ID’s interpretation of the plain meaning of “above,” the Accused Apple Watches cannot be found to infringe claim 28 of the ’502 patent. According to the ID, “the term ‘above’ ... *refers to a position relative to the device’s feature.*” While the ID observed that the “*specification* does not require any specific orientation of the device,” asserted claim 28 of the ’502 patent indisputably does: it requires a device “*configured to non-invasively measure oxygen*

*saturation.*” For the Accused Apple Watches to be “configured to” do so, they must be face up—i.e., where the position of the protrusion “relative to” the interior surface is *below*, not above.

## 2. The ID Erred In Finding The Accused Apple Watches Have “Through Holes” Or “Openings” “Through” The Protrusion.

The Accused Apple Watches also do not infringe because they lack “openings” extended or provided “*through the protrusion*” or “*through holes*” as claims 24 and 30 of the ‘648 patent, and indeed all asserted claims of the Poeze patents, require. RIB-34-39; RRB 29-34; JX-001 [’501 patent] cl. 12 [1D]; JX-002 [’502 patent] cl. 22 [19C]; JX-002 [’502 patent] cl. 28 [28F]; JX-003 [’648 patent] cl. 12 [8E]; JX-003 [’648 patent] cls. 24, 30 [20D]).<sup>25</sup> The ID clearly erred in finding Complainants had demonstrated that the Accused Apple Watches have “through holes” or “openings ... through” the protrusion based on an erroneous claim construction. The ID concluded “the ordinary meaning of the terms ‘opening’ and ‘hole’ can include openings and holes that include material.” ID 31. But when a hole is filled, then it is *no longer a hole*. While Apple does not dispute that the specification indicates that material can be placed into openings and holes, nothing in the specification indicates that once filled they *remain* “openings” or “holes”—let alone openings and holes *through* the protrusion. Neither Complainants nor Dr. Madisetti even attempted to explain how the accused openings extend “through the protrusion.” Tr. [Madisetti] 682:12-682:25; 687:16-688:8, CDX-0011C.021, CDX-0011C.022 (’502 [19C] and [19D]); *id.*

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<sup>25</sup> Should the Commission decide to review the ALJ’s non-infringement analysis as it pertains to “openings” (e.g., ID 35-38, 41-42, 46) and find non-infringement as to these limitations, then the Commission should likewise find that Complainants’ devices do not satisfy the technical prong, and in particular ’501 patent [1D], ’502 patent [28F], and ’648 patent [8E] and [20D] for the same reasons. If there are no “openings” in Apple Watch resulting in non-infringement, then there likewise cannot be any openings in any of the alleged domestic industry devices. RRB 43, 45-46; *see also* ID 66, 72, 77, 80.



690:22-691:19 CDX-0011C.026 ('502 [28F] and [28G]); *id.* 696:16-697:3, CDX-0011C.034 ('648 [8E]); *id.* 698:8-699:3; CDX-0011C.037 ('648 [20D]).

Apple's engineers, documents, and product literature all indisputably confirm that, although [REDACTED]

[REDACTED] Tr. [Warren] 1252:7-1253:3; Tr. [Block] 902:4-9; CX-0281C [Block Dep.] 272:10-274:12; CX-0291C [Mehra Dep.] 73:21-74:8; RPX-1; RPX-2; CX-68C.001]; CX-70C.001. The Accused Apple Watches do not infringe because they lack openings or holes *through* the protrusion. RIB 34-39; RRB 29-34.

**E. The Commission Should Grant Review Of The “Economic Prong.”**

The ID's analysis of the economic prong for the '648 patent (as well as for the '501, '502, and '745 patents) was legally flawed from the outset. Section 337 unmistakably requires that the Complainant demonstrate the existence of significant economic activity “related to the articles protected by the [asserted] patent.” 19 U.S.C. § 1337(a)(2), (3). As discussed above in Section IV.C, Complainants relied on five different prototypes as their DI products for the '648, '501, and '502 patents (plus another two for the '745 patent), with different groups of articles claimed to practice different claims of the asserted patents. Yet in its analysis of the economic prong, the ID treated those five separate articles as constituting one domestic industry “project” and aggregated the claimed expenditures. ID 302-04. That error alone warrants review and reversal.

The Commission should also take review of the ID's erroneous reliance on the Complainants' faulty economic prong data. At the evidentiary hearing, Complainants contended that they had incurred over [REDACTED] in expenditures attributable to the Masimo Watch prototypes. As with its asserted patent claims (only 2% of which were found to be infringed), the ALJ found nearly 90% of Complainants' claimed investments to be meritless because they were

unsupported by contemporaneous documents and based on unreliable allocations. ID 305. In total, the ID disregarded more than [REDACTED] of the claimed expenditures, leaving only [REDACTED] of claimed expenditures in plant and equipment and only [REDACTED] in labor and capital. ID 304-05, 315. Complainants' massive overreach calls into question the credibility of their entire economic prong case. Tr. [Thomas] 1288:21-1289:1. Indeed, the ID itself acknowledged that the level of Masimo's investment "can be disputed." ID 323-24.

The remaining labor and capital figures are unsupported by reliable evidence, and it was error for the ID to accept them. The central flaw was the ID's reliance on just three made-for-litigation spreadsheets as the basis for *the entirety* of Complainants' alleged expenditures on labor and capital. There is no dispute that each of these documents was created for this Investigation by Complainants' employees (Tr. [Young] 486:8-11) and that Complainants' expert merely assumed the accuracy of the data without any meaningful corroboration or analysis. Tr. [McGavock] 557:14-560:5. Moreover, the amounts they contain are not reflected in any other documents in the record, and none of Complainants' witnesses could explain with any specificity how the data underlying those numbers was obtained. *See* Tr. [Thomas] 1285:15-1286:24; Tr. [McGavock] 561:9-562:19; Tr. [Young] 486:1-7; RX-1202C [Kaufman Dep.] 33:3-33:8, 44:22-46:3, 51:1-51:9, 55:15-55:18, 57:4-11, 58:16-60:13, 61:6-61:15, 106:2-106:7.

The ID's analysis of a domestic industry "in the process" of being established is similarly flawed. It relies on the same unsubstantiated past expenditures as well as equally tenuous *projections* for future expenditures. ID 319-24. A Complainant should not be allowed to support a claim of domestic industry by performing black-box financial analyses unsupported by any contemporaneous documentation or even meaningful vetting by an independent expert. *See Certain Prod. Having Laminated Packaging, Laminated Packaging, & Components Thereof*, Inv.

No. 337-TA-874, ID 33-34 (July 5, 2013), *affirmed in relevant respects*, Comm’n Op. at 15-16 (Sept. 3, 2013) “complainants in previous investigations have been able to analyze [their] business records and allocate expenses in order to meet the Commission’s standards, regardless of the fact that that is not how business records are normally kept or how business is normally conducted”).

The ID further erred by finding the claimed [REDACTED] spending for labor and capital to be significant. Significance must be assessed “in the context of the marketplace or industry in question.” *Certain Printing & Imaging Devices & Components Thereof*, Inv. No. 337-TA-690, Comm’n Op. at 31 (Feb. 17, 2011). The ID’s finding was based on limited, self-serving testimony that the Masimo Watch was [REDACTED] [REDACTED] as demonstrated by its raw headcount in one fiscal quarter dedicated to the project. Tr. [Kiani] 126:19-23; Tr. [Young] 504:9-13; CX-0648C. And although the ID relied on the finding that all of Masimo’s claimed R&D expenditures were domestic, the value of its expenditures under subprong B (at most [REDACTED]) is a small fraction (less than [REDACTED]) of Masimo’s overall R&D spending. Tr. [Thomas] 1305:2-9. Moreover, that this project may represent Masimo’s [REDACTED] [REDACTED] not meaningful where Masimo has traditionally been focused on selling medical devices for use by clinicians and hospitals.

**1. The ID Legally Erred By Aggregating Expenditures For Claimed Domestic Industry Products That Do Not Practice Each Of The Asserted Patents.**

To satisfy the domestic industry requirement, a complainant must make the requisite showing of economic activities “related to the articles protected by the [asserted] patent.” 19 U.S.C. § 1337(a)(2). For purposes of the technical prong, Complainants asserted five different prototypes (plus the post-Complaint Masimo W1) as its domestic industry products practicing the ’648 patent (as well as the ’501, ’502, and ’745 patents). These were identified by Complainants

as the “RevA,” “RevD,” and “RevE” prototypes. ID 301-02, 303-04. Two more prototypes were asserted as domestic industry products *solely* for the ’745 patent; these were identified by Complainants as the “Circle” and “Wings” devices. *Id.* Although Complainants did *not* claim (and the ID did not find) that each of these devices practices each of the ’648, ’501, ’502, and ’745 patents, for purposes of the economic prong Complainants argued, and the ID agreed, that all seven of the prototypes could nevertheless be considered together as “iterations” of a single domestic industry “project” and expenditures related to all seven articles could be considered in the aggregate for all four patents. ID 303-04.

The ID committed legal error in aggregating expenditures across the seven different articles that Complainants claimed as domestic industry products under the technical prong, where the “different domestic [industry] products [] practice different patents.” *Certain Electronic Stud Finders*, Inv. No. 337-TA-1221, Comm’n Op. at 48 (Mar. 14, 2022). The ID cited no support for its assumption that R&D activities in 2020 were “likely to involve” developments for different groups of prototypes. ID 303. Nor was the approach justified by the observation that Masimo does not track R&D expenditures at that level of detail. *Id.* Where financial records lack the necessary detail, an alternative allocation methodology is required. *See Certain Prod. Having Laminated Packaging*, Inv. No. 337-TA-874, ID 33-34 (“complainants in previous investigations have been able to analyze [their] business records and allocate expenses in order to meet the Commission’s standards, regardless of the fact that that is not how business records are normally kept or how business is normally conducted”).

## **2. The ID Clearly Erred In Relying On Unsupported Labor Allocations.**

The ID correctly excluded more than [REDACTED] in pre-2018 expenditures that Complainants claimed in support of their domestic industry. ID 304-5. The ID’s findings were

based on its determination that the expenditures were neither supported by “specific evidence” nor “clear explanations” of the expenditures and how they related to the alleged domestic industry products. ID 305. The ID erred, however, by failing to hold the remainder of Complainants’ economic prong evidence to the same standard. Had it done so, the ID would also have disregarded the remaining [REDACTED] in labor and capital expenditures that form the basis for finding the economic prong satisfied for the ’648 family of patents. Disregarding those expenditures reduces Complainants’ claimed labor and capital investments to zero—indisputably insignificant.

The only documentary evidence cited in the ID supporting the amounts that Complainants identified as labor and capital expenditures are three made-for-litigation spreadsheets<sup>26</sup> created by Complainants’ finance group: CX-635C, the sole documentary support for [REDACTED] of alleged research and development (“R&D”) labor expenditures attributed to the Masimo Watch development project; CX-624C, the sole documentary support for [REDACTED] of alleged executive compensation attributed to the Masimo Watch project; and CX-632C, the sole documentary support for [REDACTED] of alleged recruiting compensation attributed to the Masimo Watch project. The ID relied on these spreadsheets, as well as some extremely limited and high-level testimony about them, in determining Complainants’ expenditures. *See* ID 311-312.

CX-635C—which alone accounts for more than [REDACTED] of Complainants’ economic prong expenditures—is little more than a list of [REDACTED] employees and their titles with hard-coded percentages of time allegedly spent on the Masimo Watch “project” writ large. CX-635C at LTD Labor tab; *see* Tr. [Thomas] 1298:4-1299:17. Although the time estimates were purportedly put together by Masimo engineer Ammar Al-Ali (Tr. [Al-Ali] 322:6-14), neither Mr. Al-Ali nor any

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<sup>26</sup> The ID (at 306) erroneously identifies these spreadsheets (and others) as “appendices to the complaint.” The spreadsheets were first produced as appendices to Complainants’ interrogatory responses. *See* RIB at 245; RX-1418C at 104.

other witness could testify concerning critical facts about their creation, such as what sources of data were used to compile the information. Tr. [Young] 519:21-520:7; RX-1196C [Al-Ali Dep.] 149:23-151:16; Tr. [McGavock] 561:2-12. It is not credible that Mr. Al-Ali could, up to two years after the fact and without reference to any records, provide accurate estimates of the time spent by over [REDACTED] individuals on a monthly basis for a period of nineteen months. The estimate for Mr. Al-Ali himself purports to show that he spent [REDACTED] of his time on the project each and every month throughout the calculation period, without any variation. CX-635C at LTD Labor tab, row 7. The spreadsheet also contains clear errors that call its accuracy into question. For instance, the document lists one employee, [REDACTED], twice, with different time-based allocations for the same time periods. CX-635C at LTD Labor tab, rows 70-71. Though the Commission does not require a “precise accounting,” it does require “documentation [with] sufficient detail.” *Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm’n Op. at 26 (May 16, 2008). Neither Complainants or their expert ever explained how Mr. Al-Ali allegedly made his time estimates, nor did they produce or analyze any contemporaneous records that would validate the tasks each employee performed or how they relate to the Masimo Watch project. Tr. [McGavock] 564:23-566:17; cf. ID 314 (excluding expenditures for equipment because “Complainants do not explain what it does or how it is related to any Masimo Watch prototypes”).

To support its reliance on CX-635C, the ID cited the testimony of Masimo Chief Financial Officer Micah Young. ID 312. But Mr. Young did not personally prepare any of the data compilations Complainants relied upon, and critical portions of the calculations were concededly based not on any financial records but on estimates purportedly generated by other departments (such as engineering) outside the scope of his responsibilities. See RX-1211C [Young Dep.] 9:5-18. Thus Mr. Young had no personal knowledge of the underlying data from which to attest to its

accuracy. Tr. [Young] 486:8-11. Mr. Young only testified generically that in preparing CX-635C, the leaders of engineering put together an estimate of time spent working on the Masimo Watch project and then multiplied those percentage estimates by total compensation. ID 311 (citing Tr. [Young] 492:20-493:7). Nowhere in the cited testimony does Mr. Young explain how the time allocations were prepared, what data was used to prepare them, or otherwise point to any documentation supporting the estimates. Tr. [Thomas] 1298:4-1299:5 (“I think that there needs to be more visibility into specifically what these individuals were doing. There was nobody -- Mr. McGavock failed to do anything to assess that.”).

Turning to CX-624C, Complainants’ claimed [REDACTED] in alleged executive compensation expenditures are even more tenuous. Review of CX-624C reveals that it is little more than a table with the first names of various Masimo executives and a rough “ballpark” estimate of the time they dedicated to the Masimo Watch. Notably, the percentages for each executive are the same for every quarter, demonstrating a complete lack of rigor in the document’s preparation. When asked “what methodology ... the Executive Team use[d] to determine the amount of time they spent on the project”, Complainants’ corporate representative on their economic data testified “I don’t know that.” *See* RX-1202C [Kaufman Dep.] 158:7-160:14.

Complainants produced no documents to support these percentages, nor did any executive who testified (Joe Kiani, Bilal Muhsin, and Micah Young) explain how they arrived at their time estimates. *See, e.g.*, RX-1206C [Muhsin Dep.] 129:23-130:2 (“I didn’t receive any guidance nor give it”); RX-1202C [Kaufman Dep.] 158:7-160:14 (Q. “What methodology did the Executive Team use to determine the amount of time that they spent on the project? A. I don’t know that”). Moreover, it is unclear what role several of the other executives had in the Masimo Watch project. For example, [REDACTED] RX-



1202C [Kaufman Dep.] 158:4-158:5. As Vince Thomas, Apple’s economic expert, explained, it is unclear what cognizable role the [REDACTED] could have performed with respect to R&D efforts for the Masimo Watch that would have occupied [REDACTED] of his time over a two-year period. Tr. [Thomas] 1297:11-1298:3. Although Apple raised this issue in its post-hearing brief (RIB at 269-270), neither Complainants nor the ID ever addressed it directly. *See* ID 312; CRB at 176.

Notwithstanding the lack of support, the ID concluded in a footnote that the executive compensation figures are for “managing employees working on research and development in the United States.” ID 312, n.12. But while some of the claimed time may have involved managing employees working on R&D associated with the Masimo Watch project, there is no way to determine from the record how much, if any, of the reported time was spent doing so. This concern is particularly acute in light of Complainants’ inclusion of executives (e.g., the chief of legal) for whom there is no evidence (nor reason to believe) that they were involved with R&D.

The remaining cited document, CX-632C, which serves as the exclusive basis for Complainants’ alleged [REDACTED] of expenditures on recruiting labor, suffers from the same methodological flaws as CX-635C (R&D Labor) because it is little more than a list of employees with an uncorroborated percentage of time. Complainants’ corporate representative for their financial data, Kohl Kaufman, admitted in his deposition that the percentages were provided by Masimo’s head of recruiting using nothing more than her alleged expertise. RX-1202C [Kaufman Dep.] 187:4-15. Mr. Kaufman acknowledged that the recruiting expenses were for Masimo’s engineering department generally, not specifically the Masimo Watch. *Id.* at 188:13-17.

As noted above, the ID properly excluded the vast majority of Complainants’ claimed expenditures because there was “no specific evidence in the record” describing the claimed activities and “no clear explanation of the relationship between these activities and the identified

Masimo Watch prototypes.” ID 305. If that logic had been applied consistently to the three categories of expenditures discussed above, then they too would have been excluded. Outside of line items for *monthly* time estimates in various spreadsheets that were created long after the time periods at issue, there is no specific evidence in the record describing what the engineers identified in those line items actually did during each month, nor is there any clear explanation of the relationship between whatever work they did and the identified Masimo Watch prototypes. *See Certain Electronic Stud Finders, Metal Detectors, And Electrical Scanners*, Inv. No. 337-TA-1221, Comm’n Op. at 47, EDIS Doc. ID 765331 (Mar. 14, 2022) (finding testimony from a president and COO estimating research and development cost unreliable without supporting corroborating evidence). That a person is a “Contractor – Engineer” or “Machinist” tells the Commission little to nothing about their job and how it relates to the purported domestic industry.

While the ID cited testimony from Mr. Muhsin and Mr. Scruggs to the effect that the Masimo Watch design was “continuously developed in the years leading up to the filing of the complaint” (ID 312), that statement does not substantiate the level of expenditure Complainants are claiming. Despite evidence that a number of Masimo Watch prototypes were created, on this evidentiary record there is no reliable way to determine how much was actually spent to develop them (individually or in the aggregate) because Complainants did not come forward with sufficient evidence to make that determination.

The ID (at 307-08) cited to the Commission’s decision in *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm’n Op. at 17-20, EDIS Doc. ID 649139 (June 29, 2018), to suggest that the Commission has previously relied on estimates of employee time in finding the economic prong satisfied. But in that case, there was sworn testimony that the manager provided the time estimates “based on his

intimate knowledge of the work being done at BNI...as well as his review of emails, calendar entries, and customer proposals and invoices” and “were corroborated by other employees, as evidenced by both Mr. Uriarte’s sworn testimony as well as the sworn testimony of other employees.” *Id.* at 20-21. By contrast, Complainants’ time estimates for more than ■ employees are based on the statement of *one* witness—who did not directly manage the employees—without reference to *any* documentation created in the ordinary course of business. Tacitly acknowledging the deficiency in Complainants’ records, the ID points to the Commission’s decision in *Certain Stringed Musical Instruments*, which held that the Complainant (an individual entrepreneur) was not expected to maintain records in the ordinary course of business that track activities at a project level. *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm’n Op. at 17, EDIS Doc. ID 300615 (May 16, 2008). But the Commission has not excused a Complainant—particularly a public corporation like Masimo with more than a billion dollars in annual revenue, over 1000 employees, and numerous product offerings—from coming forward with some reliable business records establishing its claimed domestic investments. *Certain Prod. Having Laminated Packaging*, Inv. No. 337-TA-874, ID 33-34. As a result, Complainants’ remaining ■ in expenditures should be disregarded.

**3. The ID Clearly Erred In Finding A Domestic Industry In The Process Of Being Established.**

With respect to the claim of a domestic industry in the process of being established, the ID erroneously concluded both that Complainants had taken “tangible steps” toward the establishment of a domestic industry and that there is “a significant likelihood that the industry requirement will be satisfied in the future.” ID 321 (quoting *Certain Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm’n Op. at 16-17). But once again, that conclusion was clearly erroneous because the financial data and forecasts that the ID relied upon are unsubstantiated.

[REDACTED]

The ID relied in part on Mr. Young’s testimony that “Masimo’s financial department “worked with engineering leaders and other Masimo employees to create a forecast of expected expenditures from the second quarter of 2021 to 2023.” ID 319. The forecasts the ID referred to are contained in Complainants’ demonstrative exhibits CDX0006.30-32, which themselves cite to underlying spreadsheets containing the projections. But the underlying forecasts are, like Complainants’ historical financial data discussed above, little more than hard-coded values unsupported by any contemporaneous documentation. For example, CDX-0006C.032 shows a simple table with columns for each quarter accompanied by an allegedly estimated number of personnel for the R&D, clinical, and quality categories, as well as estimated costs.

When Mr. Young was asked about this document at the hearing, he testified only that “we worked with the leaders of engineering and they provided a forecast of headcount, as you can see laid out here” as well as an oblique reference to using “time allocation support” to “get the labor costs forecast” without further substantive explanation. Tr. [Young] 502:7-18. Other than the unsubstantiated statements of its own employees, Complainants did not put forward any other supporting documentation of the type typically generated by a company for a major investment initiative, such as business plans or board presentations, or documentation of equipment orders, internal capital expenditure plans, or labor plans (*see* Tr. [Thomas] 1309:5-8) or otherwise explain how the projections were made. The one “forecast” document cited by Complainants at the hearing (CX-783C) was [REDACTED]

[REDACTED] See CX-783C at 7 ([REDACTED])  
[REDACTED]; ID 57 (Masimo Watch products post-date the Complaint).

[REDACTED]  
[REDACTED]  
[REDACTED]

In determining that Complainants have taken “tangible steps toward the establishment of a domestic industry,” the ID credited Complainants’ argument that it expended [REDACTED] on employment of labor and capital between 2019 and 2021. ID 322. As set forth above, the ID should not have credited those design efforts because the evidence in the record makes it impossible to ascertain what, if any, actual investments were made. *See* section IV.E.2, *supra*.

The ID also improperly relied on evidence concerning external contracts that it excluded from its analysis of an existing domestic industry. Specifically, the ID pointed to contracts “with external design firms for work on future Masimo Watch products.” ID 322. But the cited contract is with the same party [REDACTED] for which the ALJ found that there was insufficient evidence “to show activities taking place in the United States.” ID 313, 322 n.127. Because the ID found that the evidence regarding these agreements was “insufficient to show activities taking place in the United States” (ID 313), it was error to rely on them as evidence of the likelihood that a *domestic* industry was in the process of being established.

The ID also improperly credited Complainants’ projected increased hiring for the Masimo Watch. Complainants’ only evidence of “increased hiring for the Masimo Watch” is the expenditure on recruiting. ID 322. However, as previously discussed, any recruiting expenses were for Masimo’s engineering department generally, and were not specifically tied to the Masimo Watch project. RX-1202C [Kaufman Dep.] 188:13-17.

The ID’s finding that there is a significant likelihood that a qualifying domestic industry will be established in the reasonably foreseeable future is similarly flawed. The ID again erroneously relied on the same unsubstantiated projections and past expenditures discussed above. ID 322-23. The ID also pointed to Complainants’ allegation that it will allocate [REDACTED] of its Laguna Canyon Road facility for Masimo Watch manufacturing. But the ALJ found that there was *no*

The ID also brushed aside the wide variation in Masimo’s claimed projections for domestic manufacturing, which show a future domestic contribution of just [REDACTED]. ID 322-23. The ID posited that even if the domestic share were [REDACTED], that would be “likely” to support a finding of a qualifying domestic industry, citing *Certain Self-Anchoring Beverage Containers*, Inv No. 337-TA-1092, Comm’n Op. at 13 (July 4, 2019) for the proposition that “9 percent of the [annual] sales for the domestic industry product” was found to be significant. ID 323. The ID unaccountably ignored the fundamental difference between a comparison based on annual *sales revenues* and a comparison based on total *manufacturing costs*: for any viable industry, manufacturing costs should represent only a fraction of sales. Where Complainants project that [REDACTED] of their manufacturing costs will be outside of the United States, that strongly suggests that, if any industry is being established, it is not a *domestic* industry, but a principally foreign one.

**4. The ID's Finding That Complainants' Alleged Investments In Labor And Capital Were Significant Was Clearly Erroneous.**

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**First**, as discussed above, the ID incorrectly credits ██████████ in purported labor expenditures related to the Masimo Watch that were unsupported and unreliable. Because none of these expenditures should have been credited, the proper dollar amount to assess significance should have been \$0, which is plainly not significant.

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significance of Complainants' Masimo Watch-related expenditures was a list of his conclusions unsupported by any methodology or reasoning. *See* Tr. [McGavock] 544:21-454:25; CDX-0015C.012. The ID focused on only one of those conclusions for quantitative significance: that [REDACTED] percent of the total Masimo engineer headcount spent some time on the Masimo Watch project. ID 317; 315 n. 123. In isolation, that [REDACTED] of a company's engineering R&D headcount was involved in some aspect of the project (and an even lower percentage on an FTE basis, *see* ID 315-16) does not constitute a quantitatively significant investment.

*Third*, the ID's analysis was internally inconsistent. On the one hand, it relied on the relative number of R&D engineers assertedly involved at some level in the development of the Masimo Watch ([REDACTED]) with the total company R&D engineers. ID 317. But on the other hand, it concluded that a comparison of the Masimo Watch-related R&D spending with the total company R&D spending is irrelevant. *Id.* (citing *Certain Carburetors and Products Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 28, EDIS Doc. ID 692517 (Oct. 28, 2019)). In so holding, however, the ID ignores the underlying holding of *Certain Carburetors*: that significance must be based on marketplace conditions *available for consideration*. In finding the complainant's investments not significant, the ID in *Certain Carburetors* compared the percentage of the complainant's domestic industry investments to its U.S. sales of the DI product and used those sales to provide context to the value of complainant's investments. *Id.* at 9, 17-18. Complainants here cannot contextualize their investments to sales because there were no Masimo Watch sales when the Complaint was filed, nor could Mr. Young testify to the existence of more than [REDACTED] in sales even as of the date of the evidentiary hearing. Tr. [Young] 514:10-15. The only marketplace condition available for comparison is Complainants' R&D spending on the Masimo Watch as compared to its overall R&D spend. That comparison clearly shows that



Complainants' investments are not significant because, even if every one of the [REDACTED] dollars Complainants are claiming for the Masimo Watch—the majority of which the ID correctly disregards—was truly expended on the Masimo Watch, that figure represents only [REDACTED] of Masimo's total R&D spend during the relevant timeframe. *See* Tr. [Thomas] 1305:2-9.

*Fourth*, the qualitative evidence cited in the ID should be disregarded. “The Federal Circuit has clarified that qualitative factors alone are insufficient to show significant investment in plant and equipment and significant employment of labor or capital under prongs (A) and (B) of the § 337 domestic industry requirement.” *Certain Carburetors*, Comm’n Op. at 7 (citing *Lelo Inc. v. Intl Trade Comm’n*, 786 F.3d 879, 885 (Fed. Cir. 2015)) (internal quotations omitted). Given Complainants’ inability to establish quantitative significance, the qualitative significance cannot establish a domestic industry.

Regardless, the claim that the expenditures attributable to the Masimo Watch represents [REDACTED] (ID 317) was unsupported and conclusory. Complainants failed to put that assertion in perspective, neither pointing to any comparative analysis or documentary evidence to support that claim, nor explaining why such a comparison would be informative, given Masimo’s admitted historical focus on *clinical* products. Tr. [Kiani] 140:8-11. The ID’s reliance on the alleged “custom designing and building tools and equipment” and [REDACTED] as “demonstrat[ing] the importance of the Masimo Watch” (ID 318) also merits review because Complainants failed to offer any evidence to put those factors into context. This is especially true because many U.S. manufacturers utilize custom tools and [REDACTED] are common components in consumer electronics; there is no indication that Complainants’ tools, equipment, and [REDACTED] are meaningfully distinct. Nor is there evidence from which the

Commission could engage in a meaningful comparison. *See* Tr. [Thomas] 1303:11-16, 1306:14-18.

*Fifth*, the ID’s reasoning for finding that Complainants’ plant and equipment expenditures are not significant warrants a similar finding for Complainants’ labor and capital expenditures. For plant and equipment, the ID correctly identified Complainants’ failure to “place[] their plant and equipment expenditures in any appropriate context that shows significance.” This standard, supported by Commission precedent cited in the ID—*Certain Earpiece Devices and Components Thereof*, Inv. No. 337-TA-1121, Comm’n Op. at 19, EDIS Doc. ID 693820 (Nov. 8, 2019)—should be applied to Complainants’ labor and capital claims because they relied on the same type of conclusory testimony and documentation to support their plant and equipment significance claims as they did to support their labor and capital claims: they failed to demonstrate that they invested any specific amount for plant and equipment, claimed the investments are significant because they represented the [REDACTED] relied on their custom-built tools and equipment, and pointed to portions of their LCR facility purportedly dedicated to the Watch. *See, e.g.*, CDX-0015C.012. The ID inconsistently holds Complainants’ to account with respect to their plant and equipment claims while ignoring similar deficiencies in Complainants’ labor and capital claims. As to Complainants’ plant and equipment claims, the ID emphasizes that the Masimo Watch “only represent[ed] [REDACTED] of “[t]he floor space in Masimo’s headquarters.” ID 318. Such a comparison is analogous to Apple’s comparison of Masimo’s R&D investment in the Watch as compared to its overall investments, which the ID disregards.

**V. IF THE COMMISSION REVIEWS OTHER PATENTS—THOUGH IT NEED NOT—IT SHOULD CORRECT OTHER ERRORS.**

**A. U.S. PATENT NO. 10,687,745**

The ID rightly found no violation of the '745 patent based on its finding that the Accused Apple Watches do not infringe, because they do not have a material configured to change light from a first shape to a second shape. But if the Commission grants review of this patent, the Commission should find additional grounds for no violation that the ID erred in not finding.

**1. The Asserted Claims Are Invalid.**

The '745 patent claims a collection of long known, prior art components of physiological sensors arranged in standard and predictable ways. For example, conventional pulse oximeters, photodiodes, LEDs, materials that change the shape of light, light blocks, and optical shielding using dark-colored coatings were all taught by Webster and Iwamiya. Tr. [Sarrafzadeh] 1109:18-5. Plaintiffs pointed to a single purported point of novelty: changing the shape of the light emitted from the LEDs from a “first shape” to a “second shape.”<sup>27</sup> See Tr. [Al-Ali] 334:9-14 (“Q. Now, sir, you consider shaping the light to be the thing that was new about the '745 patent, correct? A. Yes.”), 335:23-24. But Apple proved that alleged novelty was not new. As the ALJ correctly found, the Iwamiya patent [RX-0130] filed five years before the '745 patent disclosed that limitation by teaching a “annular light guide unit” that changes light into an annular or ring shape. ID 225-226; *see, e.g.*, RX-0130 at 6:11-14, Fig. 4. Additionally, that limitation had been publicly disclosed by Apple Watch Series 0, whose Fresnel lens changed the shape of light emitted from certain infrared LEDs into a different, crescent shape. Tr. [Venugopal] 819:1-7, 823:1-9; Tr.

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<sup>27</sup> There is no evidence that limitation was useful. Complainants did not attempt to establish the domestic industry technical prong based on claims with that limitation. ID 199-201. Nor did Complainants demonstrate any commercial success, industry praise, or other secondary considerations tied to any asserted claims of the '745 patent. ID 240-241.

[Sarrafzadeh] 1093:3-8. Although the ID correctly found that most of the claim limitations were taught by Apple’s prior art, the ID committed clear error and legal errors in finding that a handful of limitations were missing from the prior art.

**a. Iwamiya, In View Of Sarantos And Venkatramen, Renders Claims 9, 18, And 27 Obvious.**

The ID found that Iwamiya (RX-0130) in view of Sarantos (RX-0366) and Venkatramen (RX-0368) taught the vast majority of the challenged claims 9, 18, and 27: all but Elements [9] and [18] reciting “wherein the physiological parameter comprises oxygen saturation,” and Element [27] reciting “at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light in a second wavelength, the second wavelength being different than the first wavelength.” *See* ID 224-240. However, had the ID not erred in considering Iwamiya and Sarantos, the ID would have found Elements [9], [18], and [27] disclosed by those references and found the challenged claims 9, 18, and 27 obvious.

**(1) Elements [9] and [18] – “physiological parameter comprises oxygen saturation”**

Iwamiya alone and in combination with Sarantos teaches Elements [9] and [18]. *First*, Iwamiya teaches “[a]n optical biological information detecting apparatus.” RX-0130 [Iwamiya] 1:19-42 (including, e.g., “pulse wave” or heart rate); 9:1-7. As Professor Sarrafzadeh explained, “Oxygen saturation is a biological information.” Tr. [Sarrafzadeh] 1100:2-8. Thus, Iwamiya’s disclosure alone teaches measuring biological information, which includes oxygen saturation.<sup>28</sup> However, the ID committed error by misreading Iwamiya, and committed legal error by limiting

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<sup>28</sup> Measuring oxygen saturation using light was known before either Iwamiya or the ’745 patent. *See* Tr. [Sarrafzadeh] 1107:14-16 (measuring “blood oxygenation has been known according to Webster [] since early ’80s or so”); RX-0035 [Webster] at RX-0035.0030.

Iwamiya to specific embodiments, rather than the full scope of its disclosures. *See Messerschmidt v. United States*, 14 F.3d 613 (Fed. Cir. 1993) (“A prior art reference must be considered for all that it teaches and not just for the particular invention it describes or claims.”).

For example, the ID erroneously found that “Iwamiya only discloses the use of one wavelength of light.” ID 230. But Iwamiya is not limited to embodiments with only one light source, and one wavelength. Figure 4, for example, depicts at least two different light sources (structure 6); Figure 22 depicts four different light sources. *See also* RX-0130 [Iwamiya] Figs. 4, 18-22 (depicting multiple light sources), 32:19-31 (describing “first light emitting portion 52 and the second light emitting portion 55”); 35:42-51 (“light emitting portions 55 ... are provided in four places”); RDX-7.101C (annotating RX-0130).

Moreover, claim 1 of Iwamiya teaches “a light emitting unit which emits observation light of a specific wavelength band,” and the word “[a]’ or ‘an’ in patent parlance carries the meaning of ‘one or more’ in open-ended claims containing the transitional phrase ‘comprising.’” *Free Motion Fitness, Inc. v. Cybex Int’l, Inc.*, 423 F.3d 1343, 1350 (Fed. Cir. 2005) (citation and internal quotation marks omitted). Thus, Iwamiya teaches each of one or more light emitting units having a “specific wavelength.” The ID erred in finding that Iwamiya “operates at wavelengths that are not appropriate for pulse oximetry,” but only cited a single embodiment containing an “optical filter ... configured to transmit light of a specific wavelength band of *900 nm or more* and shield light of a wavelength band of *900 nm or less*.” ID 230 (citing RX-0130 [Iwamiya] 8:42-47)). But Iwamiya is not limited to that embodiment: Claim 1 of Iwamiya, for example, recites an “optical filter” without limiting the wavelength range, and dependent claim 7 describes an optical filter different from the cited embodiment. *See* RX-0130 [Iwamiya] cls. 1, 7 (dependent claim reciting “filter transmits only light of a specific wavelength band of *800 nm or more*”).

**Second**, at minimum, Iwamiya in combination with Sarantos expressly teaches a sensor that can measure oxygen saturation. Specifically, Sarantos discloses both a heart rate sensor and an oxygen saturation sensor, explaining that PPG techniques “may also be used to measure other physiological parameters besides heart rate, such as blood oxygenation levels.” RX-0366 [Sarantos] 13:44-47; Tr. [Sarrafzadeh] 1100:9-14. A POSITA would have been motivated to combine Sarantos and Iwamiya because they are both physiological wrist-worn devices in the same field as the ’745 patent, and a POSITA would have been motivated to combine Sarantos’s teaching of a heart rate and blood oxygen measurement with Iwamiya’s teaching of measuring biological information such as heart rate (“pulse wave”). Sarantos teaches that a PPG sensor that is used to determine a heart rate can also be used to determine a blood oxygenation level, and a POSITA would have been motivated to enhance Iwamiya’s sensor by measuring blood oxygenation level. Tr. [Sarrafzadeh] 1101:11-19; RX-0130 [Iwamiya] 9:1-7; RX-0366 [Sarantos] 13:44-47. The ALJ committed legal error and clear error in concluding that Professor Sarrafzadeh’s motivation to combine testimony was “generic” because it described a desire to ““build something better.”” ID 230 (quoting *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012)). But *ActiveVideo* merely held that a motivation to “build something better” is insufficient if it “bears no relation to any specific combination of prior art elements.” 694 F.3d at 1228. Here, Professor Sarrafzadeh identified a specific combination of elements, namely, Iwamiya’s light-based sensor that measures heart rate and Sarantos’s teaching of light-based blood oxygen measurement. Moreover, Federal Circuit precedent expressly identifies “improve[ment] upon what is already generally known” as a source of “motivation” to combine. *In re Ethicon, Inc.*, 844 F.3d 1344, 1351 (Fed. Cir. 2017); *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995,

1003-1004 (Fed. Cir. 2016) (describing motivation based on seeing “advantages of applying the teachings of [one reference] to improve [second reference]”).

The ID also stated that “Apple fails to explain how the multiple emitters described in Sarantos would have been implemented in Iwamiya in a way that is compatible with the annular light guide.” ID 230 n. 84. That criticism legally errs by misapprehending the obviousness inquiry, which “does not ask whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole.” *In re Etter*, 756 F.2d 852 (Fed. Cir. 1985) (*en banc*); *In re Keller*, 642 F.2d 413 (C.C.P.A. 1981) (“[T]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into ... the primary reference.”). That criticism also clearly errs by overlooking that Iwamiya already taught using multiple light sources in conjunction with its annular light guide. *See supra* V.A.1.a.

Lastly, the ID clearly erred and legally erred in finding there would be no reasonable expectation of success in combining Iwamiya and Sarantos to measure oxygen saturation, because Apple engineers expressed skepticism in implementing pulse oximetry in a wrist-worn device. ID 231. Any skepticism would be inapposite to invalidity grounds based on Sarantos, because Sarantos expressly taught implementing pulse oximetry in a wrist-worn device. *See* Tr. [Sarrafzadeh] 1100:12-20; RX-0366 [Sarantos] 13:44-58 (“[P]hotoplethysmographic techniques may also be used to measure other physiological parameters besides heart rate, such as blood oxygenation levels”), 18:52-58 (“[T]he concepts are particularly applicable to PPG implementations for wearable fitness monitoring devices ... which are often designed to be worn as bracelets or wristbands....”). Moreover, Sarantos provides at least as much disclosure of successful wrist-based pulse oximetry as the ’745 patent—which merely states that the “measurement site [] can be any location on a patient’s body, such as ... a finger, foot, earlobe,

wrist” (’745 patent, 12:17-20)—and it is legally improper to hold Sarantos to a higher standard for expectation of success than applied to the ’745 patent for enablement. *See Publicover*, 813 F. App’x at 532 (rejecting argument that prior art was “too sparse to adequately explain to a skilled artisan” where asserted patent was “just as sparse”).

**(2) Element [27] – “at least one of the plurality of [LEDs] is configured to emit light of a first wavelength and at least one of the plurality of [LEDs] is configured to emit light in a second wavelength...”**

The ID clearly and legally erred in finding that “one of ordinary skill would [not] have been able to combine Iwamiya and Sarantos to use two wavelengths of light with reasonable expectation of success.” ID 240 (citing “same reasons discussed above [for] claim 9”); *supra* V.A.1.a.(1). The ID’s statement that the “only specific motivation for using multiple emitters disclosed in Sarantos is for measuring oxygen saturation” is wrong and clearly erroneous, because Sarantos describes using multiple emitters to “offer increased sensitivity.” RX-0366 [Sarantos] 13:28-33. The ID’s additional statement that the evidence does not show a reasonable expectation of success in modifying Iwamiya using Sarantos to measure oxygen saturation (ID 240) is erroneous for the reasons stated above. *See supra* V.A.1.a.(1). Moreover, it is legal error because Element [27] does not require successfully measuring oxygen saturation. The proper inquiry should have been whether Iwamiya can be modified to use a plurality of LEDs of at least two different wavelengths, with a reasonable expectation of success, and the evidence overwhelmingly proves the answer is yes. *See supra* V.A.1.a.(1); Tr. [Sarrafzadeh] 1109:13-17.

**b. Apple Watch Series 0 Renders Claims 9 And 27 Obvious.**

The ID found that Apple Watch Series 0 product taught the vast majority of the challenged claims 9 and 27: all but Elements [1B] and [20B] reciting, in relevant part, a “material configured to change the first shape into a second shape,” [1D] and [20D] reciting, in relevant part, a “surface



comprising a dark-colored coating,” and [9] reciting “wherein the physiological parameter comprises oxygen saturation.” ID 210-224. Although the ID correctly determined that the majority of the limitations are obvious over Apple Watch Series 0, the ID clearly erred in concluding Elements [1B], [20B], [1D], [20D], and [9] would not have been obvious. And the ID legally erred by applying a higher standard to invalidity than enablement in the patent.

**(1) Elements [1B] & [20B] – “material configured to change the first shape into a second shape”**

Apple Watch Series 0 teaches infrared LEDs with square emission surfaces, which are situated under grooves of a Fresnel lens, as shown below.



Left, RX-0392C at Fig. 2; Right, RDX-7.87 (showing grooves effect on light). Because the infrared LEDs are offset from the center of the Fresnel lens’s concentric rings, the lens changes the shape of light received from a non-crescent shape into a crescent shape. Tr. [Venugopal] 821:10-823:9; *see also* Tr. [Sarrafzadeh] 1093:3-8 (explaining light changes into a crescent shape).

The ID clearly erred in finding that Professor Sarrafzadeh’s and Apple engineer Dr. Venugopal’s testimony regarding the crescent shape were “conclusory.” ID 214. Indeed, they were anything but. Professor Sarrafzadeh explained, with reference to RX-0392, that the “Fresnel lens [shape] has these grooves as [annotated above], and these grooves take the shape of the LED [light] and transform that into a crescent type of shape.” Tr. [Sarrafzadeh] 1093:3-8. Professor Sarrafzadeh’s testimony was the opposite of conclusory because it cited specific documentary

[REDACTED]

evidence and explained how the evidence supported the change to a crescent shape. *See Intellectual Ventures I LLC v. EMC Corp.*, 786 F. App'x 1021, 1034 (Fed. Cir. 2019) (expert's declaration was "not conclusory" because it "cites to [prior art] to support his statements"). Likewise, Dr. Venugopal's testimony was not conclusory because he cited to RX-0392, explained the structure of Figure 2 that causes the crescent shape phenomenon, and explained that "[t]he infrared light, because it is not passing through an optical center, gets thrown off in a different direction, and it exits the watch and hits the skin a little bit further away [than the green LED light]. It has a crescent shape." Tr. [Venugopal] 822:5-823:9.<sup>29</sup>

**(2) Elements [1D] & [20D] – "surface comprising a dark-colored coating"**

Apple Watch Series 0 has a [REDACTED] back crystal positioned between the photodiodes and tissue, with openings below the photodiodes through which reflected light may pass. RDX-7.89C; Tr. [Sarrafzadeh] 1093:13-21; Tr. [Land] 959:3-13 (apertures through the back crystal allow light to pass through to the photodiodes). Professor Sarrafzadeh explained that the outermost portion of the [REDACTED] is a "dark-colored coating." Tr. [Sarrafzadeh] 1093:14-21. And if that does not suffice, then Dr. Sarrafzadeh also explained that it would have been obvious for a POSITA to add a dark-colored coating, which would be a simple "low-tech" addition, to ensure accurate physiological readings. Tr. [Sarrafzadeh] 1093:15-21, 1100:21-1101:10; RX-0035.0202 [Webster] (using a "black opaque material that does not transmit light" "will reduce the possibility

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<sup>29</sup> The ID also found that Apple did not explain "why Apple would have designed the Fresnel lens to change the shape of the infrared light" and such a change "is not one of the two purposes" described for the lens. ID 214. Thus, the ID implied Apple was required to show the Fresnel lens was "designed or configured to accomplish the specified objective, not simply that they can be made to serve that purpose." *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012); '745 patent, cls. 1, 20 ("material configured to"). But that standard, if properly also applied to infringement, confirms that there is no infringement because there is no evidence that Apple designed the [REDACTED] to change the shape of light. ID 191.

of false readings”). The ID erred in finding the dark-colored coating was not obvious based on Apple Watch Series 0 in view of the knowledge of the POSITA. The ID stated that Professor Sarrafzadeh “fails to identify any reason to add such a coating” (ID 216). But Professor Sarrafzadeh explained generally (and in the context of Iwamiya) that Webster “talks about black materials that are used to prevent transmission of light.” Tr. [Sarrafzadeh] 1100:22-1101:4. That knowledge and motivation also applies to adding a dark-colored coating to Apple Watch Series 0.

**(3) Element [9] – “physiological parameter comprises oxygen saturation”**

Apple Watch Series 0 monitors heart rate, and monitoring oxygen saturation is obvious based on monitoring heart rate. RX-0396C.0011 (disclosing a heart rate sensor in Series 0); Tr. [Sarrafzadeh] 1094:10-17. Both heart rate and blood oxygen saturation sensors are photoplethysmography (PPG) sensors. Tr. [Waydo] 923:12-23. Professor Sarrafzadeh explained that wrist-based pulse-oximeters were known in the 1990s, and it would have been within the skill of a POSITA to make a wrist-based oximeter by 1991, even if perfecting a commercial product would have been difficult. Tr. [Sarrafzadeh] 1095:7-16. For example, pulse oximeters have been known and commercially available since the 1970s, and pulse oximetry is the same as heart rate sensing, with the addition of comparing the amplitude of the heart rate signal at two different wavelengths of light. *Id.*; *see also id.* 1094:10-17; RX-0035.0030 [Webster] (pulse oximeters were known); Tr. [Mehra] 852:7-17 (“Q: Did your work on the blood oxygen feature for Apple Watch have anything to do with the work that you had done on the heart sensor? A. Yes, very much so. So pulse oximetry as a feature is essentially heart rate sensing, but comparing the amplitude of the signal at two different colors of light or wavelengths of light. And so all of the work that we did to design, develop, and validate heart rate sensors over multiple generations of the watch was a

great engineering base for us to build off of.”). Apple was able to draw heavily on its experience building a heart rate sensor to build a blood oxygen saturation sensor. *Id.*

The ID found that Apple would not have had a reasonable expectation of success in modifying the Series 0. ID 219. However, the ID once again legally errs by applying a higher standard to invalidity than enablement in the patent itself. *See Publicover*, 813 F. App’x at 532. The ’745 patent offers “no clear explanation of the modifications that would be necessary” as the ID requires of Apple (ID 219), yet claim 9 adds nothing to claim 1 other than the vague recitation: “wherein the physiological parameter comprises oxygen saturation.” ’745 patent, cls. 1 & 9. Indeed, claim 9 does not describe any “modifications that would be necessary” (ID 219); the ID found the Accused Apple Watches do not infringe the claim in measuring blood oxygen saturation (ID 180-199), nor do Complainants even allege they practice claim 9 (*see* ID 199).

The ID also clearly erred by overlooking Dr. Mannheimer’s testimony that the specific modification would be “putting a couple of LEDs in a Series 0 Watch form factor.” Tr. [Mannheimer] 1015:9-19. Dr. Mannheimer explained, “putting a couple of LEDs in a Series 0 Watch form factor” would “*also produce SpO2*, but not to the level that we were looking for, not to the level of reliability and accuracy, and that new design considerations would need to be developed.” *Id.* In other words, achieving pulse oximetry on the wrist was obvious; it was the design, higher reliability, and higher level of accuracy that Apple wanted that required additional invention. *Id.* And Apple ***did*** commercialize an Apple Watch (the Series 6) that measures blood oxygen saturation (SpO2). Contrary to the ID, Dr. Mannheimer’s testimony was not evidence of skepticism that blood oxygen saturation could be measured at the wrist. ID 220.

**2. No Domestic Industry—“Technical Prong”**

Complainants alleged that the technical prong of the domestic industry requirement for the ’745 patent was satisfied by eight different articles: CPX-0021C, CPX-0029C, CPX-0052C, CPX-0058C, CPX-0019C, CPX-0020C, CPX-0065C, and CPX-0146C. Similar to the Poeze patents, the ID correctly disregarded evidence of the Masimo W1, which did not exist as of the Complaint. However, the ID erred as a matter of law in finding that Complainants satisfied the technical prong requirement for the ’745 patent for similar reasons to those for the Poeze patents, including by (1) considering evidence of articles that did not exist in their current form before the Complaint and (2) relying on “circumstantial evidence” not related to any of the actual DI articles. *See* Section IV.C, *supra*. The ID also erred by relying on unsubstantiated, conclusory evidence that the prototypes contain a “light diffusing material.”

**a. The ID Erred In Considering Certain “Masimo Watch” Prototypes Despite Evidence They Were Post-Complaint.**

As explained above with respect to the Poeze patents, the evidence at the hearing showed that CPX-0058C, CPX-0019C, CPX-0020C, and CPX-0065C *did not exist* in their current form when the Complaint was filed. *See* Section IV.C.1.a, *supra*. It was therefore error to consider these devices to evaluate domestic industry.

With respect to the remaining devices, it was also error to consider either CPX-0021C or CPX-0029C (which the ID refers to as the “Circle” and “Wings” sensor, respectively, *see* ID 199). First, it is undisputed that [REDACTED] Tr. [Scruggs] 461:19-25. Second, the ID correctly found that there was no evidence that either CPX-0021C or CPX-0029C had ever been “used together with the identified Rad-97 monitor”—as required to practice claim 18 of the ’745 patent—as of the Complaint. ID 205, 207-209.

**b. The ID Erred In Finding That The Devices “Determine” Oxygen Saturation.**

As explained above with respect to the Poeze patents, the ID also erred by relying on evidence not tied to the asserted DI devices to find the technical prong satisfied for the ’745 patent. When properly limited to only evidence related to the asserted DI articles, Complainants failed to demonstrate that any of CPX-0052C, CPX-0058C, CPX-0019C, CPX-0020C and CPX-0065C actually determines a physiological parameter, let alone blood oxygen as claim 18 of the ’745 patent requires,<sup>30</sup> and the ID’s reasoning is deficient for all the reasons discussed above with respect to those devices. *See* Section IV.C, *supra*; *see also, e.g.*, Tr. [Sarrafzadeh] 1122:3-1124:23, 1125:16-1126:20; Tr. [Scruggs] 445:2-452:14; RX-1470C.

As to CPX-0021C and CPX-0029C, the ID found that these devices “measure oxygen saturation” when used with the Rad-97 monitor based on “the testimony of Mr. Scruggs and Mr. Al-Ali regarding the design, *testing*, and operation *of Masimo’s products*.” ID 205.<sup>31</sup> Again, this evidence is not related to the actual articles and therefore cannot be considered.<sup>32</sup> In any event, as

<sup>30</sup> Claim 18 depends on claim 15. Limitation 15[H] of the ’745 patent requires “a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal.” JX-0009; ID 204.

<sup>31</sup> As with the other articles relied on for the Poeze Patents, Complainants failed to offer source code related to either device that demonstrates how either device allegedly calculated oxygen saturation. ID 204-205. Dr. Sarrafzadeh explained deficiencies in the readings obtained from his observation of CPX-0021C and CPX-0029C including [REDACTED]

[REDACTED] Tr. [Sarrafzadeh] 1124:4-23; Tr. [Scruggs] 445:2-452:14; RX-1470C; Tr. [Scruggs] 448:2-449:9. Dr. Sarrafzadeh testified [REDACTED] which demonstrated that “the devices were not working properly.” Tr. [Sarrafzadeh] 1124:4-23.

<sup>32</sup> The testimony the ID cited from Mr. Al-Ali as allegedly supporting the ID’s opinion on CPX-0021C and CPX-0029C did not relate to either device. Mr. Al-Ali’s testimony at 262:7-263:10 relates to CX-0375C, which does not reflect the design of CPX-0021C or CPX-0029C. *Compare* CX-0375C *with* CPX-0021aC, CPX-0029Ac; *see* Tr. [Al-Ali] 260:11-263:10 (testifying that the sensor shown in CX-0375C is “when [Complainants] actually started doing all the calculation [of physiological parameters] within the device itself.”); Tr. [Scruggs] 403:11-14, 404:7-19; *see also* ID 60 (associating CX-0375C with “RevA”).

[REDACTED]

the ID found, “there is no evidence that [CPX-0021C (Circle) and CPX-0029C (Wings)] sensors were used together with the identified Rad-97 monitor” before the Complaint. ID 208. Thus, they cannot form the basis for the domestic industry.

**c. The ID Erred In Finding That The Devices Contain “Light Diffusing Material.”**

The ID concluded that each of the “Masimo Watch” prototypes practiced this claim limitation by relying on Mr. Scruggs’ testimony that each device purportedly contained [REDACTED] and alleged “videos and photographs” of the devices that the ALJ stated were “consistent with Mr. Scruggs’ testimony.” ID 200-201. Mr. Scruggs’ testimony cited by the ID only explained that there was a “milky color” above the LEDs—Mr. Scruggs did not say why this “milky color” was diffusing or explain anything further. Tr. [Scruggs] 400:25-401:11. Complainants did not offer a single document showing the devices contain [REDACTED]. Likewise, their expert Dr. Madisetti merely testified that he “saw how the diffusing material...was diffusing the light” (Tr. [Madisetti] 760:18-22)—but as Apple explained, no evidence proving diffused light from these demonstrations was introduced (RRB 88-91), and the ID acknowledged that Apple’s expert Dr. Sarrafzadeh “raise[d] some questions regarding the reliability of Dr. Madisetti’s analysis.” ID 201. Moreover, Dr. Sarrafzadeh explained that the mere assertion that a device contains [REDACTED] is not sufficient, as [REDACTED] is not always a diffusing material, and is present in, for example, “normal glass, and that’s obviously not a diffusing material.” Tr. [Sarrafzadeh] 1127:15-1128:8. Complainants failed to carry their burden to demonstrate that any Masimo Watch prototype contains a light diffusing material.

**3. Noninfringement**

The ID correctly determined that Accused Products have not infringed claims 9 and 27 of the ’745 patent because they do not “comprise a material configured to change the first shape [of

[REDACTED]

light] into a second shape [of light][.]” ID 180. However, the ID erroneously construed claim 1 (upon which claim 9 depends) to “not require that the emitted light has the same ‘first shape’ at the surface of the LEDs as it has at the surface of the ‘material configured to change the first shape into a second shape.’” ID 185. The ID rejected Apple’s argument that the plain language of the claim requires that the “first shape” of light received by the material—here, the [REDACTED] in the Accused Products—be the same “first shape” of light emitted by the LEDs. Instead, the ID construed “first shape” to mean “the shape of the light that is received by the light diffuser,” or the [REDACTED] ID 187. Apple requests that the Commission review the ALJ’s construction of the term “first shape.”

The ID also correctly determined that Apple has not induced infringement of claim 27 because “Complainants have not shown underlying direct infringement of the claim.” ID 199. But the ID found that Apple knew of the *alleged* infringement of claim 27 “as of the filing of the Complaint” (but not before) and “provided instructions to its users for pairing the Accused Products with Apple iPhones to monitor blood oxygen through Apple’s Health app,” and implied that these facts would be sufficient to support the knowledge and intent elements for inducement. ID 198. This was error.

**a. The ID Erred In Not Construing “First Shape” To Mean The Shape Of Emitted Light At The Emission Surface**

Claims 1 and 20 (from which asserted claims 9 and 27 depend) require a “plurality of light-emitting diodes configured to emit light in a first shape,” and the claimed material then changes the light emitted by the LEDs from “the first shape into a second shape.” JX-009 at 15:33-41; *id.* at 17:23-31. The plain meaning of “first shape” therefore refers to the shape of light as first emitted by the LEDs—*i.e.*, the shape of light at the LED emission surface. Consistent with the plain language, Figure 7A below shows that the “first shape” emitted by the LEDs is the shape of light



at the emission surface because the LED and diffuser are in direct contact with each other; as a consequence, the “first shape” of light at the emission surface of the LED is necessarily the same shape of light received by the diffuser. *See also* Tr. [Sarrafzadeh] 1112:22-1113:10 (explaining that “the shape that is ... emitted from LED [702], that exact same shape is received by the diffuser [704], because they abut each other, they touch each other”).

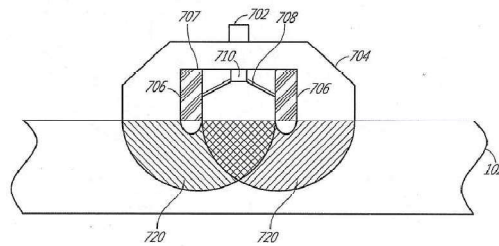


FIG. 7A

Although the ID noted that “Apple has offered a plausible interpretation of the claim language to refer to the shape of light at the surface of the LEDs,” the ID held that the “first shape” emitted by the LEDs is not the shape at the LED emission surface because “the term ‘emit’ is “not necessarily limited to the surface of the LEDs.” ID 186. To support this construction, the ID contrasted the embodiments shown in Figures 3 and 7A and noted that “the Figure 3 embodiment ... is shown with a gap between the emitter and the light diffuser,” whereas Figure 7A “does not show a gap between the emitter and the light diffuser.” *Id.*

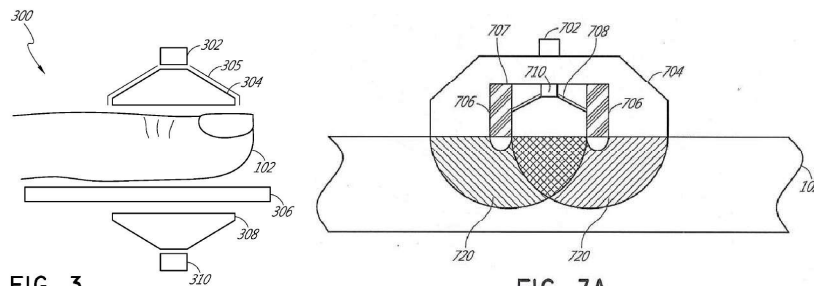


FIG. 3

FIG. 7A

The ID noted that the “same language” is used to describe both figures: “The light diffuser [304/704] receives the optical radiation emitted from the emitter [302/702] and ... spreads the

optical radiation over a[n] . . . area.” *Id.* (comparing JX-009 at 7:42-44 with 10:65-11:2). The ID’s interpretation is critically flawed.

**First**, the ID incorrectly assumes that there is a gap between emitter 302 and diffuser 304 in Figure 3, but there is no evidence in the record for the existence of such a gap. “[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.” *Hockerson-Halberstadt, Inc. v. Avia Group Int’l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000); *see also Application of Wright*, 569 F.2d 1124, 1127 (C.C.P.A. 1977) (“Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.”); Manual of Patent Examining Procedure 2125 (“Proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale.”). Here, although the specification does not provide quantitative measurements as to the distance, if any, between emitter 302 and diffuser 304, Figure 3 depicts gaps between **every** component, including between reflector 305 (described as a “coating, film, layer, or other type of reflector”) and diffuser 304, and between tissue 102 and detector 306. The specification states that one purpose of reflector 305 is to “prevent light piping that might occur if light from the detector 302 is able to escape from the light diffuser 304 . . . .” *See* JX-009 at 7:23-25. Reflector 305 could not act as a “coating, film, layer, or other type of reflector” to “prevent light piping” if it is separated by a gap from diffuser 304. That is, while not-to-scale Figure 3 shows space between reflector 305 and diffuser 304, a POSITA would understand that the spacing is an artifact of the drawing and that the device would have no such spacing. A POSITA would understand the same about LED 302 and diffuser 304. Thus, the ID erred in construing “first shape” based on this perceived distinction between Figure 3 (depicting gap between emitter and detector) and Figure 7 (no gap depicted). *See Plantronics, Inc. v. Aliph*,

*Inc.*, 724 F.3d 1343, 1351 (Fed. Cir. 2013) (holding that “the figures in the [asserted patent] do not evidence actual dimensions” and therefore “they cannot be relied upon to argue that the disputed terms should be limited to a particular structure”).

**Second**, the ID’s reliance on Figure 3 to support her construction of “first shape” is flawed because Figure 3—unlike Figure 7A—does not depict a claimed embodiment. Asserted claims 9 and 27 require that the claimed physiological monitoring device have a reflectance configuration. *See* JX-009 at 15:47-57 (“...wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light **reflected** from the tissue to pass through the surface”); *see also id.* at 5:35-37 (requiring that the claimed material “be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user”). Figure 3 depicts a physiological monitor in a transmittance configuration, *i.e.*, light emitted from emitter 302 is transmitted through tissue 102 before being received by detector 310, and is not an embodiment of the asserted claims. By contrast, Figure 7A depicts “a reflective three-dimensional pulse oximetry sensor,” *id.* at 5:28-29, as required by the asserted claims. Here, the ID failed to identify any “‘highly persuasive’ evidence” needed to support a “claim interpretation that excludes a preferred embodiment from the scope of the claim,” and ID’s reliance on Figure 3 was in error. *CUPP Computing AS v. Trend Micro Inc.*, 53 F.4<sup>th</sup> 1376, 1381 (quoting *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 1583-1584 (Fed. Cir. 1996), and *Accept Packaging, Inc. v. Leggett & Platt, Inc.* 707 F.3d 1318, 1326 (Fed. Cir. 2013)).

**b. The ID Erred In Finding That Apple Had Requisite Knowledge Of Alleged Infringement**

Though the ID correctly held that Apple has not induced infringement claim 27, Apple requests that the Commission review the ID’s finding that that Apple “knew of the alleged infringement of claim 27 as of the filing of the Complaint” sufficient to support the knowledge

and intent elements of inducement. ID 198. Specifically, the ID found that the Complaint “contained allegations of infringement (including a claim chart for claim 27) similar to the evidence presented at the hearing.” *Id.* But to support this finding, the ID cites only Complaint Exhibit 18, filed on June 30, 2021, and no other evidence. *Id.* This lone citation does not satisfy the “preponderance of evidence” standard, particularly where Complainants identified no testimony from any witness (including their own expert Dr. Madisetti) that Apple had the requisite knowledge to support a finding of induced infringement. *See* RIB at 173; RRB at 88. Citation to *Certain Beverage Brewing Capsules*, Inv. No. 337-TA-929, Comm’n Op. at 19-21 (Apr. 5, 2016), is also inapt because Complainants failed to show by a preponderance of evidence that the “infringement allegations set forth in [their Complaint] claim charts are substantially similar to [] ultimate infringement findings” (*id.*), nor can they because Dr. Madisetti heavily relies on his post-complaint testing results to attempt to prove infringement.

#### **4. The Economic Prong Is Not Satisfied.**

Because it relies on overlapping groups of devices, the ID’s finding that the economic prong was satisfied for the ’745 patent is clear error for the same reasons as the Poeze patents. *See* Section IV.E, *supra*.

#### **5. The ’745 Patent Is Unenforceable.**

For the reasons discussed in Apple’s initial post-hearing brief (RIB at 204-205) and consistent with Federal Circuit precedent, as recently confirmed in *Personalized Media Communications v. Apple, Inc.*, Case No. 21-2275, Dkt. 49 (Fed. Cir. Jan. 20, 2023), the ID erred in its finding that Apple had not shown the asserted Poeze patents unenforceable under the doctrine of prosecution laches and/or unclean hands. Complainants’ five-year delay and strategy of waiting until Apple further developed its technology and fostered the market for wearable technology was

both unreasonable and prejudicial to Apple who invested heavily in developing that technology and growing the market while Masimo inexcusably delayed its prosecution.

**B. U.S. PATENT NO. 7,761,127**

The ID rightly found no violation of U.S. Patent No. 7,761,127 (“’127 patent”) based on its correct claim constructions and finding that the Accused Apple Watches do not infringe over those constructions. But if the Commission grants review of to this patent, it should correct errors in the ID’s technical prong, invalidity and economic prong analyses.

**1. The Early Rainbow Sensor Do No Satisfy The Technical Prong.**

Complainants alleged that two product groups—(1) the “early rainbow® sensors” that [REDACTED] and (2) the “current rainbow® sensors [that] use a [REDACTED] [REDACTED]—practice claim 9 of the ’127 patent for purposes of the domestic industry, technical prong requirement. ID 273-275; CIB 36, 266-274. The ID correctly determined that Complainants failed to show that the Current Rainbow Sensors meet Element 7[A], which requires a “thermal mass” that stabilizes a bulk temperature, and Element 7[F], which requires that the temperature sensor be “capable of determining a bulk temperature for the thermal mass” that is a representative temperature for the thermal mass. ID 256, 259, 275-277, 279-281. However, the ID clearly erred in finding that the Early Rainbow Sensors meet the “thermal mass” and “bulk temperature for the thermal mass” limitations (ID 281, 279-281).

**a. Early Rainbow Sensors Do Not Meet “Thermal Mass” Limitation.**

The ID clearly erred in finding that the Early Rainbow Sensors satisfy the “thermal mass” limitation. *First*, the ID erred in assuming that Mr. Diab’s testimony regarding his simulations using [REDACTED] software on a prototype “model of [a] sensor” (Tr. [Diab] 200:14-16; 201:2-202:2) applied to actual Early Rainbow Sensors. ID 276. Mr. Diab never testified that his simulations

had anything to do with the actual Early Rainbow Sensors. If anything, Mr. Diab's testimony established that the simulations were of prototype sensors different from Early Rainbow Sensors. For example, Mr. Diab stated that the "model" shown in CX-0342C has only [REDACTED] Tr. [Diab] 201:10-11 [REDACTED] CX-0342C at 6 [REDACTED]). Mr. Diab expressly contrasted his software simulations on prototype "models" with different, spectrometer-based "experiments on actual sensors," (Tr. [Diab] 203:7-204:1), [REDACTED] Tr. [Diab] 196:3-6; *see also* Tr. [Goldberg] 629:21-25 ("I [REDACTED] There is *zero* evidence linking (A) the design and thermal properties of the "model of [a] sensor" referenced in Mr. Diab's [REDACTED] simulation testimony, with (B) the design and thermal properties of actual Early Rainbow Sensors.

None of the ID's citations establishes that linkage either. The ID cited Mr. Diab's testimony (ID 276 (citing Tr. [Diab] 216:15-218:21)), but that testimony only described CX-397C, which confirms there are [REDACTED] in the Early Rainbow Sensors (whereas what Mr. Diab simulated had only [REDACTED]). Tr. [Diab] 216:15; CX-0397C [Early Rainbow Sensor drawing] (listing nine LEDs). The ID also cited CX-0588C (ID 276), which depicts the thickness of an Early Rainbow Sensor circuit board, but there is no evidence comparing that board with the different, unlabeled drawing in CX-0342C at 6.<sup>33</sup> The ID also relied on Mr. Diab's deposition testimony that [REDACTED] (ID 276 (citing RX-1200C at 110:7-112:1), but that testimony again only described CX-0588C. RX-1200C at 107:11-16, 110:6-112:1 (discussing MASITC00974332 [CX-0588C])). That deposition testimony did not relate to the [REDACTED]

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<sup>33</sup> The ID erroneously relied on Mr. Diab's deposition testimony that Complainants [REDACTED] (ID 276 (citing RX-1200C at 110:7-112:1)). That testimony did not relate to the prototype "model" board simulated in CX-0342C at 6. RX-1200C at 107:11-16, 110:6-112:1 (discussing CX-0588C). Thus, Mr. Diab's deposition testimony could not establish that the "model" board in the simulation is representative of the actual Early Rainbow Sensor boards.

██████████ “model” board in CX-0342C or whether any simulation data in CX-0342C could be extrapolated to different boards that also have ██████████. Finally, the ID credited Mr. Diab’s testimony that the “wavelength of the LEDs could be accurately determined” in the Early Rainbow Sensors (ID 276-277 (citing Tr. [Diab] 203:7-204:11)), but that testimony is inapposite, because it does not involve whether a mass stabilizes a bulk temperature.

*Second*, the ID erred by relying on the insufficient, conclusory, and unsupported testimony of Mr. Diab to conclude that the Early Rainbow Sensors meet the “thermal mass” limitation. *See TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1357 (Fed. Cir. 2019) (reversing agency decisions because “the [agency’s] factfinding is based on conclusory testimony and is therefore unsupported by substantial evidence”); ID 276-277. Mr. Diab described conducting a “simulation” of a “model of [a] sensor where you can input ... some of the properties [], run the LED, put some heat in it, and watch the result.” Tr. [Diab] 200:14-202:2 (describing results in CX-0342C at 6 and 30). Mr. Diab testified that the figure at CX-0342C at 6 depicted a “distribution of the heat,” but he never in any way suggested that it depicted temperature stabilization. Tr. [Diab] 201:19-20. As for CX-0342C at 30, he stated: “you can see that the temperature of the thermal mass following and fairly stabilizing along with the temperature of the LED...” *Id.* at 201:2-203:6. Mr. Diab never testified that the mass stabilizes a **bulk** temperature, i.e., a **representative** temperature for the entire thermal mass. *See id.* Nor does the documentary evidence corroborate that the mass stabilizes at any temperature, because line “b” is a curve, not a horizontal line.

In sum, Mr. Diab’s testimony regarding ██████████ simulations on a prototype sensor do not apply to the Early Rainbow Sensors, and Complainants failed to present evidence regarding bulk temperature stabilization in Early Rainbow Sensors. In fact, Complainants’ expert conceded that he conducted no “testing whatsoever of ... the Early Rainbow Sensors,” including to determine

“whether the [REDACTED] of the Early Rainbow Sensor[s] stabilized a bulk temperature.” Tr. [Goldberg] 655:9-657:7); *see also* Tr. [Sarrafzadeh] 1069:23-1070:9 (“some form of experiment, simulation or emulation” is needed); *Yoon Ja Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1320 (Fed. Cir. 2006) (rejecting conclusory testimony and noting failure “to determine whether [accused elements] had the required effect”). Professor Sarrafzadeh rightly concluded that Mr. Goldberg “did not” show that the [REDACTED] “act as a thermal mass” or show that any components “stabilize a temperature.” Tr. [Sarrafzadeh] 1084:22-1086:10.

**b. Early Rainbow Sensors Do Not Meet “Bulk Temperature” Limitation.**

The ID also clearly erred in finding that the Early Rainbow Sensors satisfy the “bulk temperature for the thermal mass” limitation. As discussed above with respect to the “thermal mass” limitation, Mr. Diab’s testimony and the simulation results shown in CX-0342C do not describe the prototype’s thermal mass stabilizing a bulk or representative temperature for the thermal mass, and additionally the testimony and simulation results are inapplicable to the Early Rainbow Sensors. *See supra* V.B.1.a. And Complainants’ expert, Mr. Goldberg, conducted “no testing of any rainbow sensors” and therefore “has no foundation” to verify that any bulk temperature is measured in the Rainbow Sensors. Tr. [Goldberg] 655:23; Tr. [Mehra] 892:11-893:6 (Complainants’ counsel arguing that witness “has no foundation” to testify whether thermistor measures “the average temperature of the [REDACTED]” because “he would need to establish that he has knowledge of the average temperature of the board and that he has made such measurements”). Thus, there is a complete failure of proof that a thermistor in the Early Rainbow Sensors is capable of measuring the “bulk temperature for the thermal mass.”

None of the ID’s citations shows that the Early Rainbow Sensors’ thermistor is capable of measuring the “bulk temperature for the thermal mass,” *i.e.*, a representative temperature for the



thermal mass. *First*, the ID stated that Mr. Diab's simulation results showed a [REDACTED] [REDACTED] ID 280 (quoting Tr. [Diab] 201:19-203:6)). Even assuming the simulations apply to actual Early Rainbow Sensors (and they do not), there was no testimony that the simulation's temperature line was a bulk temperature or representative temperature of the mass, as opposed to a local temperature on the mass that happened to correlate with the LEDs. Although Apple noted that a bulk temperature "'*could be* measured by a properly positioned single thermistor if the thermal mass were stabilized at the bulk temperature,'" (ID 281 (quoting Apple's RRB at 122)), in all other cases a single thermistor measures a "local temperature." Tr. [Sarrafzadeh] 1086:11-21; RX-1195C-.0034 [Abdul-Hafiz] 99:1-99:5 ("Local temperature is where you put the thermostat."); Tr. [Goldberg] 647:17-20 ("Like all temperature sensors," thermistors "measure the temperature in the region in which they're located"). There was no evidence of the representative temperature of the mass in either the simulations or the Early Rainbow Sensors, and that the thermistor measured that representative temperature. *Second*, the ID relied on Mr. Diab's testimony that the thermistor temperature in the Early Rainbow Sensors was used to determine LED operating wavelengths. ID 280-281 (citing Tr. [Diab] 203:7-204:11). But that testimony regarding the *subsequent use* of the thermistor measurement in Early Rainbow Sensors does not demonstrate that the *nature* of the thermistor measurement is the bulk or representative temperature for the thermal mass. *See also* ID 259 (recognizing that a construction requiring only that "the bulk temperature be used to estimate the operating wavelengths of all the LEDs would be met by [the prior art], which does not include a 'thermal mass'").

As Professor Sarrafzadeh confirmed, the evidence shows that the Rainbow Sensors' thermistor "measures the resistance of the resistor of the thermistor present" which is a "local temperature," and Mr. Goldberg offered no evidence that a thermistor on the Rainbow Sensors

[REDACTED] Tr.  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] Tr.  
[Sarrafzadeh] 1086:11-25; CX- 0430C at 6 (“measure the resistance of the resistor or thermistor present”). The “bulk temperature for the thermal mass” limitation is thus not met.

## **2. Claim 9 Of The '127 Patent Is Invalid.**

The '127 patent claims a collection of long known, prior art components of physiological sensors arranged and used in standard and predictable ways. For example, conventional pulse oximeters, photodiodes, thermistors, LEDs, LED substrates, ceramic substrates, multilayered circuit boards, circuit boards with thermal cores, LED wavelength dependence on temperature, and wavelength calibration using a temperature sensor were known. RX-0458 [Mendelson] Fig. 10.16; RX- 0035.0085 [Webster]; RX-0381 [Yamada] at [0111]; RX-0353 [Noguchi] 1:38-50; Tr. [Goldberg] 1403:13-1404:4 (substrates, circuit boards); RX-0397 [Scarlett]. The only two limitations the ID did not locate in the prior art under its correct constructions were Elements [7A], requiring a “thermal mass” that stabilizes a bulk temperature,<sup>34</sup> and Element [7F], requiring a temperature sensor “capable of determining a bulk temperature for the thermal mass,” *i.e.*, a representative temperature for the thermal mass. ID 284-299. However, those limitations were rendered obvious by the prior art, and the ID clearly erred in finding otherwise. And should Complainants’ misguided approaches to construing those limitations, infringement, and the domestic industry technical prong somehow be adopted, then Claim 9 would be obvious.

### **a. Mendelson, In View Of Webster, Renders Claim 9 Obvious.**

The ID found Mendelson teaches Elements [7preamble], [7B], [7C], [7E], [7G], [7H], and [9]. ID 283-292. For Element 7[D], the ID found Mendelson did not teach this limitation based

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<sup>34</sup> The ID also found that Element 7[D], requiring the “thermal mass [be] disposed within the substrate,” was not met by the prior art based only on the lack of a predicate “thermal mass.” ID 289.

only on the finding that the “thermal mass” limitation (Element 7[A]) was not taught. Under at least Complainants’ strained interpretations of “thermal mass” and “bulk temperature for the thermal mass,” however, the remaining limitations of Elements [7A], 7[D], and [7F] would be taught by Mendelson, Webster, and the knowledge of a POSITA (as evidenced by, e.g., Scarlett).

**(1) Element [7A] – “thermal mass”**

As shown in Mendelson’s Figure 10.16, Mendelson discloses LEDs and photodiodes mounted on a ceramic substrate, which is another name for a circuit board or printed circuit board. RX-0458 [Mendelson] Fig. 10.16; Tr. [Sarrafzadeh] 1049:24-1050:6. Professor Sarrafzadeh explained that a POSITA would have understood Mendelson’s ceramic substrate could be implemented as a conventional multilayer circuit board with metal layers. Tr. [Sarrafzadeh] 1050:7-1051:12, 1053:1-8. Complainants erroneously contend that the metal layers of the printed circuit boards of the Accused Apple Watches are the claimed thermal mass. Tr. [Goldberg] 617:9-21. Even indulging that erroneous view, Mendelson renders obvious a printed circuit board with multiple layers. Tr. [Sarrafzadeh] 1050:25-1051:12. Professor Sarrafzadeh also explained that a POSITA would have found it obvious, been motivated, and had a reasonable expectation of success based on Scarlett to implement Mendelson’s ceramic substrate as a circuit board with a more significant “metal core or thermal core for better [thermal] management.” *Id.* at 1050:13-1051:12 (noting Scarlett’s metal core “provides thermal management”). Therefore, the ID clearly erred in overlooking that Mendelson renders the claimed “thermal mass” obvious under a view of the “thermal mass” as a thermal core. And certainly under Complainants’ erroneous infringement

theory of alleging metal layers of a conventional multilayered circuit board satisfies the “thermal mass” limitation, Mendelson would render such a structure obvious.<sup>35</sup>

**(2) Element [7F] – temperature sensor “capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature”**

Mendelson in combination with Webster teaches the claimed temperature sensor “capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature.” Webster discloses using a temperature sensor built into the probe to compensate for errors in SpO2 readings that can occur due to shifts in LED wavelengths caused by temperature changes. Tr. [Sarrafzadeh] 1053:23-1054:11; RX-0035.0085 [Webster]. Professor Sarrafzadeh testified that, in view of Webster, a POSITA would have found it obvious to measure a bulk or representative temperature for the thermal mass, for example by using multiple temperature sensors at multiple locations of the thermal mass. Tr. [Sarrafzadeh] 1053:23-1054:11. A POSITA would have been motivated to combine Mendelson and Webster; both are related to physiological monitoring systems and are in the same field as the ’127 patent. Tr. [Sarrafzadeh] 1056:6-15, RX-0458 [Mendelson] Fig. 1016 (describing a noninvasive reflection blood oxygen sensor), RX-0035 [Webster] at Title (“Design of Pulse Oximeters”). A POSITA would have been motivated to use the temperature sensor of Webster to improve the functionality of the pulse

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<sup>35</sup> Even under Complainants’ new and equally erroneous infringement theory that the “thermal mass” is assumed if a temperature measurement is used to reliably estimate operating wavelengths of LEDs, Mendelson in view of Webster teaches the addition of a temperature sensor to “compensate for LED temperature changes” such that [t]emperature information is fed back to the microprocessor, which then estimates how much the peak wavelength of each LED has changed from its rated value.” RX-0035.0085 [Webster] (citing Cheung); ID 289-290; *see also* ID 254-256 (noting that even Cheung would teach a “thermal mass” under Complainants’ erroneous theory) (citing RX-0406 [Cheung]).

oximeter of Mendelson by increasing the accuracy of the wavelength estimation, and would have had a reasonable expectation of success in doing so. Tr. [Sarrafzadeh] 1056:11-15, 1056:16-23.

The ID believed that Webster taught away from adding more than one temperature sensor (ID 291 n.112), but that misread Webster and was clear error. Webster taught that a “cost-benefit analysis” would apply if additional sensors or wires are added, not that such additions should not be made. RX-0035.0085-.086 [Webster]. But even with Webster’s single temperature sensor, Mendelson in view of Webster would teach Element [7F] at least under Complainants’ erroneous view that a bulk temperature is measured when a single temperature is used to estimate the operating wavelength of all the LEDs. *See* RX-0035.0074, 0083-.086 [Webster]; Tr. [Sarrafzadeh] 1054:14-18, *see also* Tr. [Sarrafzadeh] 1053:23-1055:3; ID 254-256 (describing Cheung, which is cited by Webster).

**b. Yamada, In View Of Noguchi, Renders Claim 9 Obvious.**

As the ID found, there is no dispute that Yamada teaches Elements [7preamble], [7B], [7C], [7E], [7G], [7H], and [9]. ID 292-299. However, the ID clearly erred in finding that Elements [7A] and [7F] were not taught by Yamada combined with Noguchi. As for Element 7[D], the ID found Yamada did not teach this limitation only based on its finding that the “thermal mass” limitation (Element 7[A]) was not taught. ID 295. And should Complainants’ erroneous interpretations of “thermal mass” and “bulk temperature for the thermal mass” be accepted, the remaining limitations of Elements [7A], [7F], and [7D] would certainly be taught by Yamada in view of Noguchi and the knowledge of a skilled artisan.

**(1) Element [7A] – “thermal mass”**

Figure 5 of Yamada (RX-0381, Fig. 5) shows LEDs and photodiodes mounted on a printed circuit board. Tr. [Sarrafzadeh] 1058:8-19. Electrical connections provide power to the LEDs and photodiodes and serve to thermally couple the components. *Id.*

A POSITA would have understood to implement the circuit board of Yamada with a thermal core. *Id.* For example, a POSITA would use a thermal core to provide thermal management for the circuit board, as taught by Scarlett (RX-0397). *Id.* at 1058:9-19, 1059:17-25. Such a thermal core would have furthered Yamada’s goal of “dispers[ing] heat” using thermal conductors. RX-0381 [Yamada] ¶¶101-102. A POSITA also would have understood to implement the circuit board of Yamada as a multilayer printed circuit board, which is what Complainants erroneously allege is the claimed thermal mass in the Accused Apple Watches. Tr. [Goldberg] 617:9-21. Even assuming that erroneous allegation, Yamada renders obvious a printed circuit board with multiple layers. Tr. [Sarrafzadeh] 1058:8-19. Therefore, Yamada renders the claimed “thermal mass” obvious under a view of the “thermal mass” as a thermal core, and the ID clearly erred in concluding otherwise. Moreover, Yamada would also render the limitation obvious under Complainants’ erroneous theory that metal layers of a conventional multilayered circuit board satisfy the “thermal mass” limitation.

**(2) Element [7F] – temperature sensor “capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature”**

Yamada discloses a temperature sensor attached to the light probe on the surface of the LED substrate. Tr. [Sarrafzadeh] 1060:8-17; RX-0381 [Yamada] at [0109]. In view of Yamada’s disclosure, a POSITA would have found it obvious to measure a bulk temperature for the thermal mass, for example, by using multiple temperature sensors. Tr. [Sarrafzadeh] 1060:8-17. Noguchi explains that LED operating wavelengths depend on temperature, as a property of physics. RX-

0353 [Noguchi] 2:59-68; Tr. [Sarrafzadeh] 1057:21-1058:1. Noguchi also teaches using a temperature measurement means or a plurality of temperature measurement means to measure “the temperature of an LED” or “the temperature in the environment in which the LED is disposed.” Tr. [Sarrafzadeh] 1060:25-1061:9; RX-0353 [Noguchi] 1:38-50. A POSITA would have used Noguchi’s teachings that LED wavelength is a function of temperature in order to provide better wavelength estimation for Yamada’s pulse oximeter. *See* Tr. [Sarrafzadeh] 1061:10-15. A POSITA would have found it obvious to combine Yamada with Noguchi because Yamada is related to using a pulse oximeter and performing physiological measurements, while Noguchi explains the impact of temperature on LED wavelengths in a sensor. *Id.* 1061:17-22, 1057:21-1058:1; RX-0353 [Noguchi] 1:7-12 (describing the invention being used in “an LED light source for a sensor”). A POSITA would have been motivated to improve the functionality of Yamada’s pulse oximeter by adapting Yamada’s temperature sensor using Noguchi’s teachings, with a reasonable expectation of success. Tr. [Sarrafzadeh] 1061:23-1062:8; RX-0035.0122 [Webster] (“As the wavelengths of the LEDs depend on the temperatures, for accurate measurements the effects of the temperatures must [] be known”), .0085 (“One way to compensate for LED temperature changes is to have a temperature sensor built into the probe along with the LEDs”); RX-0353 [Noguchi] 1:7-12 (“The present invention relates to an apparatus and method for controlling the emission spectrum of an LED”). Thus, the combination of Yamada and Noguchi taught the measurement of a bulk or representative temperature.

The ID stated that Yamada measures temperature for a different purpose (ID 297), but that finding was clear error because it overlooked the motivation supplied by Noguchi to use temperature measurements in order to provide a better wavelength estimation for Yamada’s pulse oximetry calculation. Tr. [Sarrafzadeh] 1061:10-15. The ID also found that Noguchi does not

[REDACTED]

[REDACTED]

[REDACTED]

describe measuring a representative temperature for the thermal mass (ID 298), but that too was clearly erroneous. Professor Sarrafzadeh explained that a POSITA would have found it obvious to measure a representative temperature by using multiple temperature sensors.

Moreover, at least under Complainants' erroneous view that a bulk temperature is measured when a single temperature is used to estimate the operating wavelength of all the LEDs, Yamada in view of Noguchi would teach Element [7F]. There is no dispute that Yamada expressly discloses at least one temperature sensor. RX-0381 ¶ 111, Fig. 50. And Noguchi taught, as a POSITA well-understood, both the measurement of "the temperature of an LED" or "temperature in the environment in which the LED is disposed," as well as the dependence of LED wavelength on temperature. RX-0353 [Noguchi] 1:38-50, 2:59-68; RX-0035.0085, .0122 [Webster].

**c. The ID Legally Erred In Finding Secondary Considerations Of Non-Obviousness.**

The ID found there was evidence of commercial success and industry praise for the '127, but found that "Complainants' evidence for nexus is weak." ID 300. The only nexus evidence the ALJ relied on was a conclusory statement by a named inventor, and Complainants' employee, that [REDACTED] ID 300-301 (citing Tr. [Diab] 204:2-11). But even that testimony cannot support a nexus as a matter of law, because Mr. Diab did not identify the "thermal mass" and "bulk temperature" limitations—the only limitations the ALJ found inventive (albeit [REDACTED] [REDACTED] commercial success, or praise. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 n.6 (Fed. Cir. 2012) ("[C]ourts must exercise care in assessing proffered evidence of objective considerations, giving such evidence weight *only where the objective indicia are attributable to the inventive characteristics* of the discovery...."). Moreover, Mr. Diab's testimony is entitled to no weight for nexus purposes



because “‘secondary considerations’ provide evidence of how the patented device is view by the interested public: *not the inventor.*” *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.* 119 F.3d 953, 957 (Fed. Cir. 1997); ID 201. Thus, secondary considerations do not support non-obviousness and the ID’s contrary finding was legal error.

### 3. The Economic Prong Is Not Satisfied.

The ID’s contingent findings that Complainants’ expenditures attributed to the Rainbow products were reliable and significant are clearly erroneous. The ID correctly held that Complainants failed to establish the threshold step of identifying any existing articles under the technical prong that practice the ’127 patent, “preclud[ing] any reliable domestic industry analysis.” ID 325. The ID nevertheless made contingent findings under the economic prong in the event the Commission were to reverse the technical prong finding. ID 327-35. Apple respectfully submits that the ID’s contingent economic prong findings are clearly erroneous and warrant review should the Commission reach that issue.

Section 337 requires that Complainants identify *specific* article(s) that practice each asserted patent. *Microsoft*, 731 F.3d at 1361-62 (“A company seeking section 337 protection must therefore provide evidence that its substantial domestic investment—e.g., in research and development—relates to *an actual article that practices the patent ....*”) (emphasis added). While the ID correctly held that Complainants failed to “allocate their domestic industry expenditures” (ID 325) “to the articles protected by the patent” (19 U.S.C. §1337(a)), it incorrectly found some of Complainants’ expenditures to be reliable and significant. ID 327-35. Complainants’ claimed expenditures, however, have been calculated and considered in the aggregate, without any analysis or allocation to “early” or “current” sensors—let alone any specific purportedly practicing article. *Electronic Stud Finders*, Inv. No. 337-TA-1221, Comm’n Op. at 48 (rejecting an economic prong

analysis that aggregated expenditures across practicing and non-practicing products). The ID incorrectly credits Complainants' unallocated expenditures, thus erring in its reliability and significance findings.

**a. Complainants' Claimed Expenditures Attributed to Rainbow Sensors Are Unreliable.**

As with the Masimo Watch, Complainants' claimed expenditures rely almost exclusively on their made-for-litigation appendices; Complainants do not offer corroborating documents or testimony supporting the data contained in the appendices, the methods employed in preparing them, or the reliability of the information, including the calculations and allocations used. For the reasons discussed in Section IV.E.2 above with respect to the Masimo Watch labor and capital expenditures, these appendices should be disregarded. However, if they are not, the ID further erred in relying on the appendices because the expenditures therein—that the ID credits—are expenditures generally attributed to the broad category of Rainbow sensors. Both Complainants' plant and equipment and labor and capital-related expenditures should therefore be disregarded.

The ID acknowledges that Complainants' expenditures for plant and equipment “may not be precise” but still finds Complainants' asserted expenditures “sufficiently reliable for the domestic industry analysis.” ID 327-29. Even assuming the costs identified in the litigation-created appendices are accurate, the expenditures identified in the ID (and by Complainants) represent aggregated costs of multiple Rainbow sensors. Not only do Complainants fail to identify the expenditures for “early” or “current” sensors but, as discussed *supra* in Section V.B.1 with respect to the technical prong, because Complainants fail to even identify *which* sensors *could* even be considered practicing, Complainants cannot establish that any of these credited expenditures actually relates to a patent practicing article.

Complainants' evidence of the claimed labor and capital expenditures further exemplify their failure to allocate expenditures to specific patent practicing articles. **First**, as with the Masimo Watch, Complainants rely on "time allocations" to support their R&D expenditures, which, for the reasons described in Section IV.E.2, *supra*, should be disregarded. Moreover, Complainants applied those time allocations against Masimo's overall R&D expenses reported on Masimo's 10-K. Tr. [Young] 500:8-22; Tr. [Thomas] 1309:16-1310:3 ("For example, they do a calculation of Masimo R&D, and that amounts to [REDACTED] of investment. It's the exact same type of calculation they did for the watch, the wrist-worn R&D, where they just take an amount from their 10-K and apply a percentage, and, in my opinion, I think that's inappropriate."). This is the *same* approach employed by Complainants to calculate their pre-2018 "wrist-worn" R&D, which the ID correctly disregarded. ID 305 (disregarding "Masimo's 'wrist-worn' research ... [because] Complainants have provided no clear explanation of the relationship between these activities and the identified Masimo Watch prototypes" and because "[t]he Commission has held that merely identifying expenditures with respect to general product lines is not sufficient to account for expenditures 'with respect to' domestic industry articles"). Not only did Complainants not allocate expenditures based on any specific patent practicing articles, but Complainants also attempted to use time generally related to the "rainbow" technology as a whole in seeking to establish satisfaction of the economic prong.

**Second**, the ID's crediting of certain Cercacor R&D projects also ignored Complainants' failure to properly allocate expenditures to patent practicing articles. ID 332-33. The ID credited [REDACTED]-related expenses, for instance, because that project [REDACTED] and credits Ember-related expenses because it "incorporates [rainbow] technologies." ID 332. But neither the ID nor

Complainants established that [REDACTED] or Ember have anything to do with the *patent-practicing* rainbow® sensors. Ember is a commercialized product, but Complainants made no showing that it practices the '127 patent. The ID erred as a matter of law in including expenditures for [REDACTED] and the Ember product to the domestic industry for the '127 patent. *See Certain Subsea Telecomm. Sys. and Components Thereof*, Inv. No. 337-TA-1098, Comm'n Op. at 41, EDIS Doc. ID 691678 (Oct. 21, 2019).

**b. Complainants' Claimed Expenditures Attributed To The Rainbow Sensors Are Not Significant.**

The ID correctly concluded that Complainants failed to offer any reliable support that their plant and equipment expenditures were significant. ID 329. The ID should have similarly determined that the Complainants' purported labor and capital expenditures were not significant.

For quantitative significance, the ID cited to Cercacor's total net R&D expenses. ID 333. But, as discussed above, this ignored Complainants' failure to establish that each of the claimed expenditures actually related to the purportedly patent practicing article. Because Complainants failed to do so, it is impossible to reliably claim that the expenditures the ID identified as quantitatively significant were indeed incurred for the practicing article. The issue is not simply that "Complainants' expenditures are overstated and unreliable" (ID 333), but also that because Complainants failed to even establish *which* expenditures relate to a practicing article the ID could not conduct a reliable quantitative significance analysis.<sup>36</sup>

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<sup>36</sup> This failure to establish an appropriate comparative framework also explains why Apple's comparison of rainbow® product revenues against Masimo's total product revenues is apt. *See* ID 335 (disregarding comparison). Because Complainants have incorrectly rested their economic prong case on the rainbow sensor category as a whole, the only available metric for comparison is against Masimo's overall revenues.

With respect to qualitative significance, the ID again relied on the general importance of Complainants' "rainbow" technology. ID 334 (finding that Cercacor's R&D effort related to the *rainbow technology* has been a large part of its business); *id.* (considering CX-633C which purports to show that "Cercacor has dedicated between [REDACTED] and [REDACTED] of its employees to *rainbow*®"); (highlighting that Masimo made "investments in R&D labor for *rainbow*®" and "manufactures important components of the *rainbow*® sensors"). The ID cited no evidence—nor could it—linking those expenditures to the asserted DI products. In fact, the cases cited in the ID each required more detailed evidence of domestic activities *tied to the DI Product* than Complainants provided and the ID could cite. *See, e.g., Certain Percussive Massage Devices*, Inv. No. 337-TA-1206, Comm'n Op. at 14, EDIS Doc. ID 759545 (Jan. 4, 2022) (crediting evidence of the following domestic activities "*directed toward the DI Products*": "research and development, design, engineering, supply chain and operation management, sales, marketing, warranty, customer service, executive, intellectual property protection, and other business operations") (emphasis added); *Certain Toner Supply Containers and Components Thereof (II)*, Inv. No. 337-TA-1260, Comm'n Op. at 11-12, EDIS Doc. ID 777011 (Aug. 3, 2022) (crediting evidence of "core manufacturing activities" in part because the patent practicing component of the DI article was manufactured in the United States). The ID should not have found that Complainants met their burden of proof.

### C. THE POEZE PATENTS

The ID correctly found no violation of either the '501 or '502 patents or claim '12 of the '648 patent. If the Commission corrects for the ID's errors with respect to the technical prong or non-infringement with respect to the '648 patent (*see* Sections IV.C, IV.D, *supra*), there could be no violation of any Poeze patent claim. If the Commission does not take review and correct for

those errors however, it should review the following errors in the ID's invalidity analysis pertaining to the Poeze patents.

**1. The Asserted Claims Are Invalid.**

**The ID clearly erred in finding that Lumidigm does not disclose a “convex protrusion” (all asserted Poeze claims).** ID 88, 97. Lumidigm discloses a “compound curvature on the optical surface” of its protrusion “to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured.” *See* RX-0411 at 7:57-63, 8:1-4, 8:27-28. A POSITA would have understood that a sensor with “compound curvature on the optical surface” has a convex protrusion. Tr. [Warren] 1205:12-1206:7; 1210:12-1211:8. Indeed, Lumidigm explicitly discloses that the sensor surface “can be contoured to fit specific product applications and ergonomic requirements.” RX-0411 at 8:27-28.

**The ID clearly erred in finding “optically transparent material within each of the openings” was not disclosed by Lumidigm or rendered obvious by its teachings (’502 claim 22).** ID 121-124. The ID correctly determined Lumidigm “clearly discloses ‘optically transparent material’ over openings.” *See* ID 123. Indeed, Lumidigm teaches an optical relay to “transfer[] the light from the light sources to the skin and from the skin back to the detector(s) while minimizing light loss and spreading.” RX-0411 at 8:19-26; Tr. [Warren] 1221:16-1222:25, 1235:14-1236:2. A POSITA would have understood an optical relay (such as “fiber optic face plates,” “individual optical fibers,” or “fiber bundles) could be added to Lumidigm’s sensor. RX-0411 at 8:19-26, Fig. 2; Tr. [Warren] 1221:16-1222:25. A POSITA would have further understood the optical relay could be placed over or within the openings to “transfer light” from the tissue to the photodiodes and “protect the detector from dust and debris and dirt.” RX-0411 at 1193:24-1194:7, Tr. [Warren] 1221:16-1222:16. The “fiber bundles,” for example, would be placed within

the openings and used “to essentially direct light from a portion of the tissue straight to the detector as a means to optimize the detection process. Tr. [Warren] 1222:10-16

**The ID clearly erred in finding Lumidigm in combination with Cramer does not render “optically transparent material within each of the openings” obvious.** The use of optically transparent materials extending across or within opening associated with photodiodes was well known in the art prior to 2008 and taught by Lumidigm. Tr. [Warren] 1221:16-12:22-9, 1193:24-1194:14; RX-0411 at 8:19-26, Fig. 2. A POSITA would have naturally looked to other references in the field to improve on Lumidigm’s teachings and would recognize the CLT 2160 taught by Cramer as a “can” detector and would understand that each can would include a lens at the top end of the can, that the detector would be positioned inside the can at the focal point of the lens, and that there would be a gap between the detector and the lens, creating an opening between the detector and the lens. RX-0670 at Fig 6; Tr. [Warren] 1231:23-1232:9, 1234:3-8, 1234:22-1235:12. A POSITA would have been motivated to combine Lumidigm with Cramer because Lumidigm expressly teaches the benefits of transparent material within openings over photodiodes and, more generally, because the benefits were well known. Tr. [Warren] 1235:14-1236:2.

**The ID clearly erred in finding Apple’s combinations including Apple ’047 <sup>37</sup> do not render “touch-screen” obvious (’502 claim 28).** ID 133-136. Once again, the ID focused on the wrong issue – namely, whether a touch screen could be physically incorporated into the face of the wristwatch. ID 136. The asserted Poeze claims neither recite nor require such a structure. Nor could they: The Poeze specification does not disclose or enable such a structure. Indeed, the specification references the potential for a touch screen only twice as a purely hypothetical

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<sup>37</sup> Apple offered two combinations that render ’502 claim 28 obvious: (1) Lumidigm + Webster + Apple ’047 and/or (2) Lumidigm + Seiko 131 + Cramer + Webster + Apple ’047.

alternative (JX-0001 at 15:60, 17:25) and *all* the embodiments depict the display attached to but *separate from* the user-worn portion of the device (*id.* at Fig. 2A-D). *See Etter*, 756 F.2d at 859; *Allied*, 825 F.3d at 1381; *Sneed*, 710 F.2d at 1550; *Moultet*, 686 F.3d at 1333-34. The ID also incorrectly found that Professor Warren failed to identify a motivation. To the contrary, he confirmed a person would have been motivated to make the combination because this was a “well-known mechanism” for a display. Tr. [Warren] 1240:8-17.

**The ID clearly erred in finding written description support for the claimed combinations (all claims).** The Poeze specification fails to disclose a single embodiment containing all the claimed limitations. While the ID identified various limitations dispersed throughout the specification, it erroneously found that they belong to the same embodiment by citing to generic language providing that one embodiment can mix-and-match between different sensors. The ID’s finding cannot be squared with its treatment of the prior art, and specifically Lumidigm, which expressly confirms that its wristwatch embodiment can include *any* of the disclosed sensor geometries. RX-0411 at 11:64-12:2. This contrast is particularly significant given that combining different elements of the prior art is *permitted* when determining whether the prior art teaches the claimed invention, but it is *not* permitted when analyzing whether the asserted patent provides an adequate written description. *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, at \*3-4 (Fed. Cir. July 14, 2021) (“[T]he specification must present each claim as an ‘integrated whole.’ ... A patent owner cannot show written description support by picking and choosing claim elements from different embodiments...”).

**The ID clearly erred in finding enablement of a touch screen (‘502 claim 28).** ID 166. The ’502 specification provides no guidance on how to use a touchscreen that “displays indicia responsive” to any “measurement,” nor provides any guidance on how to implement a touchscreen



in a user-worn device. RRB 75-76. The ID, again, erroneously imposed a higher scrutiny in its obviousness analysis compared to its analysis here. Here, the ID found the scant references to a touch screen in the Poeze specification sufficiently enables a touch screen on a user-worn device but failed to find the same when examining the prior-art—which is arguably more detailed with respect to touch screens. ID 133-36. The ID was also inconsistent in its treatment of the underlying testimony. While the ID credited Dr. Madisetti’s enablement explanation—where he simply recited a list of specification citations and concluded they are enabling—the ID described Dr. Warren’s testimony on the subject as “conclusory,” despite providing more explanation than Dr. Madisetti. *See* Tr. [Warren] 1226:22-1227:7, 1240:4-1242:9, 1241:1-17; RDX-8.83-84; Tr. [Madisetti] 1352:5-24; 1381:7-1382:8 (testimony cited by the ID concerning touch screens).

**The ID clearly erred in finding enablement for avoiding and reducing “light piping” (’501 claim 12, ’502 claim 28, ’648 claim 24) and sufficient written description support for substantially preventing light piping (’648 claim 24).** ID 169. The Poeze specification provides no guidance on how to avoid, reduce, or manage the problem of “light piping” aside from general reference to opaque materials. Tr. [Warren] 1247:24-1248:4. The specification fails to explain when “light piping” has been “substantially” prevented, how a POSITA accomplishes or determine this, and how the sensors were constructed to accomplish this limitation.

## **2. The Poeze patents Are Unenforceable.**

For the reasons discussed in Apple’s initial post-hearing brief (RIB at 153-159) and consistent with Federal Circuit precedent regarding, as recently confirmed in *Personalized Media Communications* (No. 21-2275, Fed. Cir. Jan. 20, 2023), the ID erred in its finding that Apple had not shown the asserted Poeze patents unenforceable under the doctrine of prosecution laches and/or

unclean hands. Complainants' twelve-year delay in filing the applications for the asserted Poeze patents was both unreasonable and prejudicial to Apple.

## **VI. CONCLUSION**

For the foregoing reasons, Apple respectfully requests the Commission review and reverse the ALJ's erroneous conclusions concerning validity, infringement, technical DI, and economic DI for '648 patent. Should the Commission take review of issues relating to the other patents—though it need not do so—Apple further requests that the Commission review the additional issues set forth in this Petition.

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U.S. International Trade Commission  
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Washington DC, 20436

**Re: Inv. No. 337-TA-1276**

Dear Mr. Traud,

- I represent non-party Adam Waddell, MD. I am submitting this response to the Commission's solicitation of comments on public interest issues raised by the ALJ's recommendations for relief in Investigation No. 337-TA-1276. The recommended relief is in the public interest given the need to protect the patent rights of medical device innovators from the threat of companies such as Apple who can afford to infringe as a mere cost of doing business.
- Explain a little about your organization or personal reason for your interest in the matter
  - **I work as a neuro-intensivist at Hartford Hospital in Hartford, CT.**
- I am concerned that if Masimo's intellectual property were not respected and enforced, that would necessarily drive reduced innovation from the company. The oxygen saturation measurement feature found in the Apple Watch is not intended for medical use/medical grade/peer reviewed.
- I believe if a company with the size, resources, and reputation of Apple is allowed to trample on an innovator's technology, this will for decades hamper innovation, including at Masimo.
- I commend the work already devoted to this important issue, and urge the Commission to confirm the violation and enter the exclusion order and cease and desist against the infringing Apple Watches.

Sincerely,

Adam Waddell, MD

A handwritten signature in black ink, appearing to be 'AW' followed by a long, sweeping flourish that extends upwards and to the right.

**Appx23751**

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya  
Administrative Law Judge**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**COMPLAINANTS' RESPONSE TO APPLE INC.'S PETITION FOR REVIEW OF THE  
FINAL INITIAL DETERMINATION ON VIOLATION OF SECTION 337**

[REDACTED]

Pursuant to Commission Rule 210.43, Complainants Masimo Corporation and Cercacor Laboratories, Inc. (“Complainants” or “Masimo”) respectfully submit this Response to Respondent Apple Inc.’s (“Apple” or “Respondent”) Petition for Review of the Administrative Law Judge’s Final Initial Determination on Violation of Section 337 (EDIS Doc. ID 788470).

### **I. RESPONSE TO APPLE’S INTRODUCTION**

Apple improperly tries to tempt the Commission to grant review based on what Apple believes is the “simplest path” to bring this Investigation to conclusion. RPR at 3. But Apple never adheres to the standard of review to show any legal or factual error in any of the detailed findings set forth in the ID. As a result, Apple’s petition is rife with new arguments, defenses, and theories.

Apple has virtually no argument supporting noninfringement of the Poeze Patents. Its noninfringement arguments boil down to a few frivolous claim construction arguments concerning the meaning of ordinary words such as “over,” “above,” and “openings.” The ID fully considered and correctly rejected those arguments and applied the plain and ordinary meaning for all of the disputed terms. And because the characteristics of the accused Apple Watches are undisputed, the ID correctly found infringement of each and every Poeze Patent claim.

With no genuine noninfringement argument, Apple primarily relies on its invalidity arguments. More specifically, Apple argues that the Poeze Patent claims are invalid for obviousness based on Lumidigm. In making its obviousness arguments, Apple misdirects the Commission to “IPR proceedings involving the larger family” of patents sharing a specification with the Poeze Patents. Apple trumpets that those IPR proceedings had over a 99% “IPR failure rate” and shows “profound invalidity problems” with the Poeze Patents. RPR at 2. Apple concludes that the failure rate “speaks to the fundamental problems arising from Complainants’ efforts to stretch their patent portfolio to try to reach Apple’s products.” *Id.* But Apple never

[REDACTED]

explains how those IPRs relate to the patent claims at issue in this Investigation. Rather, as Masimo's CEO and its expert witness explained at the hearing when confronted by Apple with its IPR-failure-rate theory, those IPRs involve different patents, different claims, different prior art, and different invalidity arguments.

After the hearing, the ALJ rejected Apple's attempt to make those IPR decisions and related documents of record when it had not relied on them previously. Order No. 57 at 5, EDIS Doc. ID 779168 (Aug. 31, 2022). The ALJ also struck from Apple's post-hearing briefs various arguments concerning these IPRs in part because Apple *failed to show the relevance* of those IPRs to the claims in this Investigation. *Id.* Apple argues the ALJ erred by not taking judicial notice of those IPR decisions and requests that the Commission do so because those decisions reflect Masimo's failure rate before the Patent Office. RPR at 9 n.4.

With regard to the Poeze Patents asserted in this Investigation, since the hearing, Apple has filed six IPR petitions attacking the validity of all three Poeze Patents for obviousness. *Id.* Apple requests that the Commission take judicial notice of those new IPR proceedings, in which institution decisions were "to be expected shortly." *Id.* Apple's request for judicial notice reflects Apple's position before the Commission that the Patent Office is the "lead agency in assessing patentability, or validity, of proposed or issued claims." Inv. No. 337-TA-1266, Apple Emergency Motion to Commission, EDIS Doc. ID 785898 at 1, 8 (Dec. 7, 2022).

Since Apple filed its petition here, the Patent Office denied *all six* of Apple's IPR petitions on the Poeze Patents. Thus, Apple failed to show a reasonable likelihood it would prevail with respect to any claim. *See* 35 U.S.C. § 314(a). In all six IPR decisions, the Patent Office rejected Apple's invalidity arguments, many of which relied on the very same references Apple raised in this Investigation, particularly Lumidigm. With regard to the '648 Patent and Lumidigm, the

[REDACTED]

Patent Office expressly found “that none of the prior art on which [Apple] relies discloses a convex protrusion with multiple openings *or* windows for multiple detectors.”<sup>1</sup> Appx. A at 17. The Patent Office rejected Apple’s “proposed amalgamation of prior art teachings” as a “convoluted combination” that was “grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art.” *Id.* at 18-19. The Patent Office held “we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.” *Id.* at 17 (quoting *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017)). The Patent Office similarly rejected Apple’s attacks on the ’501 and ’502 Patents as grounded in hindsight, where Apple improperly stitched together the prior art using the claimed inventions as its guide. Appx. B at 15-16; Appx. C at 15-16.<sup>2</sup>

Unlike the “failure rate” trumpeted by Apple for different patents, the only failure rate relevant here is Apple’s failure rate on the six asserted Poeze Patent claims. And Apple lost in all six of its separate petitions on the Poeze Patents. Masimo agrees with Apple that the Commission take judicial notice of the six IPR decisions because those decisions concern the very same claims and prior art before the Commission. RPR at 9 n.4. And, in view of Apple’s firm position before the Commission that the Patent Office is the “lead agency in assessing patentability, or validity, of proposed or issued claims,” (Inv. No. 337-TA-1266, Apple Emergency Motion to Commission, EDIS Doc. ID 785898 at 1, 8 (Dec. 7, 2022)), Apple should drop its requests for review on the Poeze Patents. Apple should also now agree with Masimo that the ID erred in finding Claim 12 of the ’501 Patent invalid for obviousness.

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<sup>1</sup> All emphasis added unless indicated otherwise.

<sup>2</sup> For the reasons explained in Masimo’s Petition for Review (CPR at 6-23), and as set forth in the Patent Office’s denials of institution of IPR for the ’501 Patent (Appxs. A, D), the Commission should reverse the ID’s conclusion that Claim 12 of the ’501 Patent is invalid for obviousness.



[REDACTED]

shown above, the testimony is about the engineers' skepticism [REDACTED] of Apple's efforts to add an oxygen saturation feature to the Apple Watch. For example, Mannheimer testified [REDACTED] Tr. (Mannheimer) at 994:11-995:11, 1012:12-16. Despite decades of pulse oximetry design experience, Mannheimer's reaction to that project was [REDACTED] *Id.* at 1012:17-22. Mannheimer did not qualify his skepticism based on industrial design or anything else. *Id.* at 1012:12-1013:6. Rather, he testified that the wrist was just "enormously different from the physiological perspective than more conventional sites for pulse oximetry." *Id.* at 1013:1-4. The ID thus correctly considered Apple's argument and rejected it based on the actual testimony of its engineers. ID at 114-115 (rejecting Apple's argument that "the delays [in implementing pulse oximetry in the Apple Watch] were related to aesthetic standards, including the small form factor and industrial design limitations"). Indeed, the ID correctly found the "testimony at issue indicates broader signal issues." ID at 117 n.42.

As shown above, the record extended well beyond expert testimony, and Masimo thoroughly rebutted all of Apple's evidence. Nothing suggests the ID made any error when considering all of the evidence in concluding that a POSITA would not have been able to measure oxygen saturation with Lumidigm's wristwatch at the time of the Poeze Patents.

**c. Apple Waived Its New Enablement and Written Description Arguments, Which Are Legally Incorrect and Unsupported**

Because Apple cannot seriously challenge the ID's finding concerning the deficiencies of Lumidigm, Apple attempts to misuse that finding to raise new invalidity challenges to the Poeze Patents. Apple's new invalidity attack is that the Poeze Patent specifications lack enablement and written description for measuring oxygen saturation at the wrist. Apple argues that the ID legally

[REDACTED]

erred “by requiring more enabling disclosure from the prior art than the asserted patent itself provides.” RPR at 15-16. Specifically, Apple incorrectly argues that because the ID found that Lumidigm does not enable measuring oxygen saturation with a wristwatch, “the asserted claims would themselves be invalid for failure to describe or enable their full scope.” RPR at 17. That argument is waived, legally incorrect, and factually unsupported.

i. **Apple Waived Its New Enablement and Written Description Theories**

Apple *never argued* at any stage of this Investigation that the Poeze Patents failed to enable *or* provide adequate written description for the claim element of a user-worn device configured to measure oxygen saturation. *See* RIB at 147-153 (raising no such argument); RRB at 73-76 (same); RPHB at 126-130 (same). Thus, pursuant to this Investigation’s Ground Rules 9.2 and 13.1, Apple indisputably waived the enablement and written description arguments it now attempts to raise. EDIS Doc. ID 752396 at 16, 26-27. Federal Circuit and Commission precedent confirm that Apple waived these new arguments. *See, e.g., Broadcom Corp. v. Int’l Trade Comm’n*, 542 F.3d 894, 901 (Fed. Cir. 2008); *Certain Marine Sonar Imaging Sys.*, Inv. No. 337-TA-926, Comm’n Op., 2019 WL 10630508, at \*27 (Feb. 1, 2019); *Certain Optical Disk Controller Chips and Chipsets*, Inv. No. 337-TA-506, Comm’n Op. at 20-21, EDIS Doc. ID 260477 (Sept. 28, 2005); *Certain Display Controllers*, Inv. No. 337-TA-491, Comm’n Op. at 36, EDIS Doc. ID 223531 (Feb. 4, 2005). Apple’s waived arguments cannot show any error in the ID, and the Commission should disregard them. *See Lannom Mfg. Co., Inc. v. U.S. Int’l Trade Comm’n*, 799 F.2d 1572, 1580 (Fed. Cir. 1986) (vacating waived invalidity finding because “Congress did not authorize the Commission to redetermine patent validity when no defense of invalidity has been raised.”); *Certain Ground Fault Circuit Interrupters*, Inv. No. 337-TA-739, Comm’n Op. at 24 (June 8,

[REDACTED]

2012) (citing *Lannom* in declining to analyze waived invalidity argument). The Commission should reject Apple’s new arguments on this basis alone.

**ii. Apple’s New Theories Are Legally Incorrect**

Even if Apple had not waived its new enablement and written description arguments, any consideration of them would show they are legally incorrect for multiple reasons. First, Apple improperly lumps together the enablement and written description requirements into what it calls “enabling written description.” RPR at 10, 12, 16-17. But Apple’s phrase conflates two distinct legal requirements: enablement and written description. *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc) (“hold[ing] that § 112, first paragraph, contains two separate description requirements: a ‘written description (i) of the invention, *and* (ii) of the manner and process of making and using the invention.’”) (emphasis in original); *see, e.g., Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1191 (Fed. Cir. 2014) (explaining differences between written description and enablement requirements). Because neither defense was raised below with respect to this claim element, Apple never attempted to show that the Poeze Patents lack written description or lack enablement for a user-worn device configured to measure oxygen saturation. And, had Apple raised such defenses, Masimo would have had an opportunity to rebut such arguments with fact and expert testimony and evidence.

Apple never explains how the ID’s finding that Lumidigm lacks enablement could be probative of a lack of written description in a completely different specification. RPR at 10, 12, 16-17. Nor could such a comparison be relevant to written description, which considers “the four corners of the specification from the perspective of a [POSITA].” *Ariad*, 598 F.3d at 1351. The disclosure of Lumidigm provides no analysis of the written description support for the Poeze Patent claims.

[REDACTED]

Apple next tries to create a new rule of patent law based on what it calls “several black letter legal principles” and “governing law” regarding enablement. RPR at 10-11. Apple’s new rule is that “the asserted patent(s) specification must contain a **more robust** disclosure that describes and enable[s] **all** claimed embodiments, and the prior art need only describe and enable **one** embodiment.” RPR at 11. Apple’s rule violates several basic canons of patent law and raises new factual questions never argued or developed below.

**First**, a patent does not have to enable all claimed embodiments. *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (“[T]he enablement requirement is met if the description enables **any** mode of making and using the invention.”) (internal citation omitted). Nor does a patent need written description for every “conceivable and possible” embodiment encompassed by its claims. *Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003).

**Second**, while it is true that the prior art must describe and enable an embodiment that falls within the scope of the claims to invalidate such claims, the ID correctly found that the prior art did not enable any such embodiment. ID at 114-118.

**Third**, in patent infringement litigation or ITC investigations, after the court or ALJ issues their decision, lawyers cannot then begin to compare disclosures to determine whether the patent specification is “more robust” than the prior art. Apple misleads the Commission because its case law—which concerns the prosecution and examination of patent applications before the Patent Office—does not justify Apple’s post-decision comparison of Lumidigm with the Poeze Patents’ specification. *Id.* at 2, 5, 10-11, 16-17, 98 (relying on *In re Publicover*, *In re Epstein*, and *In re Paulsen*).

[REDACTED]

teachings” as a “convoluted combination” that was “grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art.” *Id.* at 16-17. In doing so, the Patent Office correctly explained that “we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.” *Id.* at 17 (quoting *Metalcraft*, 848 F.3d at 1367). Additionally, the Patent Office rejected Apple’s hindsight-driven obviousness arguments in denying institution of another IPR petition where Apple relied on a combination of Lumidigm with Apple ’047 and other references to challenge a ’648 Patent claim that requires a touch-screen display similar to ’502 Patent Claim 28. Appx. A at 9-10. The Patent Office’s decisions confirm that the ID correctly rejected Apple’s obviousness arguments for ’502 Patent Element [28K].

**5. The ID Correctly Rejected Apple’s Written-Description Challenge to the Claimed Combination of Features**

The ID correctly found that “the evidence fails to show, clearly and convincingly, that the asserted claims reciting three or more LEDs, three or more photodiodes, and a protrusion with a plurality of openings over the photodiodes with opaque lateral surfaces lack written description.” ID at 159-160. Apple criticizes the ID for relying on the specification to “mix-and-match between different sensors.” RPR at 98. Apple’s attempted comparison of Lumidigm with the Poeze Patents’ specification is incorrect and waived as explained above. *Supra* Section III.A.1.c. Moreover, Apple incorrectly relies on *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, at \*3-4 (Fed. Cir. July 14, 2021). Apple omits the Federal Circuit’s explanation that “[a] patent owner cannot show written description support by picking and choosing claim elements from different embodiments that are *never linked together in the specification.*” *Id.* But the ID correctly found that the Poeze Patents’ specification expressly links its embodiments of sensors 101, 201, 301, and 701: “[t]he specification of the Poeze patents expressly states that Figure 3C

[REDACTED]

and Figure 7B are not distinct embodiments—“[t]he features of the sensors 701 can be implemented with any of the sensors 101, 201, 301 described above.” ID at 159 (quoting JX-0001 at 26:25-26).

**6. The ID Correctly Rejected Apple’s Argument That the Poeze Specification Did Not Enable the Claimed Touch-Screen Display (’502 Patent Claim 28)**

Apple criticizes the ID’s correct finding that the Poeze Patents’ specification enable the claimed touch-screen. RPR at 98-99 (citing ID at 166). Apple criticizes the ID for requiring more detail from Lumidigm than from the Poeze Patents’ specification. *Id.* (citing ID at 133-136). But Apple never made that argument below and thus waived it. RIB at 152 (raising no such argument); RRB at 75-76 (same). That argument is also legally incorrect for the reasons explained above. *Supra* Section III.A.1.c. Apple also ignores that the claimed touch-screen requires displaying “indicia responsive” to a measurement of oxygen saturation. Lumidigm includes no disclosure regarding that requirement. *See, e.g.*, ID at 133. The ID correctly weighed the relevant evidence from Madisetti and the specification, and explained that “Apple has not presented any arguments regarding the majority of the *Wands* factors” to show lack of enablement. ID at 166. The ID correctly concluded that Apple failed to carry its burden. ID at 168.

**7. The ID Correctly Rejected Apple’s Argument That the Poeze Patents’ Specification Lacks Written Description Support For and Does Not Enable the Features to Avoid, Reduce, and Prevent Light Piping**

Apple tersely criticizes the ID’s correct findings regarding written description for and enablement of the claimed features to avoid, reduce, and prevent light piping. RPR at 99. But Apple merely cites to the same single sentence of Warren testimony that the ID already criticized as insufficient to meet Apple’s burden. ID at 169. Apple ignores the ID’s analysis of the teachings in the specification. *See* ID at 169 (citing JX-0001 at 7:65-8:7, FIG. 3, 43:30-33, 43:33-36, FIGS. 7A-7B, 27:1-3, 25:43-65). Apple provides no record evidence that could carry its burden.

# APPENDIX A

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Paper 15  
Entered: January 30, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APPLE INC.,  
Petitioner,

v.

MASIMO CORPORATION,  
Patent Owner.

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IPR2022-01276  
Patent 10,945,648 B2

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Before JOSIAH C. COCKS, NEIL T. POWELL, and JAMES A TARTAL,  
*Administrative Patent Judges.*

POWELL, *Administrative Patent Judge.*

DECISION  
Denying Institution of *Inter Partes* Review  
35 U.S.C. § 314



IPR2022-01276  
Patent 10,945,648 B2

## I. INTRODUCTION

### A. BACKGROUND

Apple Inc. (“Petitioner”) filed a Petition for *inter partes* review of claims 1–30 of U.S. Patent No. 10,945,648 B2 (Ex. 1001, “the ’648 patent”). Paper 2 (“Pet.”). Masimo Corporation (“Patent Owner”) filed a Preliminary Response. Paper 10 (“Prelim. Resp.”).

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the Petition and any response thereto shows “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner does not show a reasonable likelihood that at least one of the challenged claims is unpatentable. Accordingly, we do not institute *inter partes* review.

### B. RELATED PROCEEDINGS

The parties note that the ’648 patent is involved in *Masimo Corporation, et al. v. Apple Inc.*, ITC Inv. No. 337-TA-1276. Pet. 94; Paper 5, 1. *Apple Inc. v. Masimo Corporation and Sound United, LLC*, U.S. District Court for the District of Delaware, Case No. 1:22-cv-01378-MN. Paper 14, 1. The parties also identify a number of related *inter partes* review proceedings. Pet. 95; Paper 5, 3. Additionally, Patent Owner identifies a number of related patents, patent applications, and litigations involving related patents. Paper 5, 1–4.

### C. THE ’648 PATENT

The ’648 patent discusses devices using spectroscopic analysis in patient monitoring. Ex. 1001, 2:14–19. These devices may have at least a

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light source that sends light into or off a measurement site, such as flesh with blood pulsing through it. *Id.* at 2:16–19. A photo-detection device detects attenuated light from the measurement site, generating a signal in response to the detected light. *Id.* at 2:19–22. The signal is processed by a signal processing device to produce data for monitoring a patient's condition. *Id.* at 2:25–28. For example, the signal processing device may indicate “a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, or other physiological parameters.” *Id.*

An example system for measuring one or more blood analytes noninvasively appears in Figure 1. *Id.* at 5:41–44. Figure 1 is reproduced below.

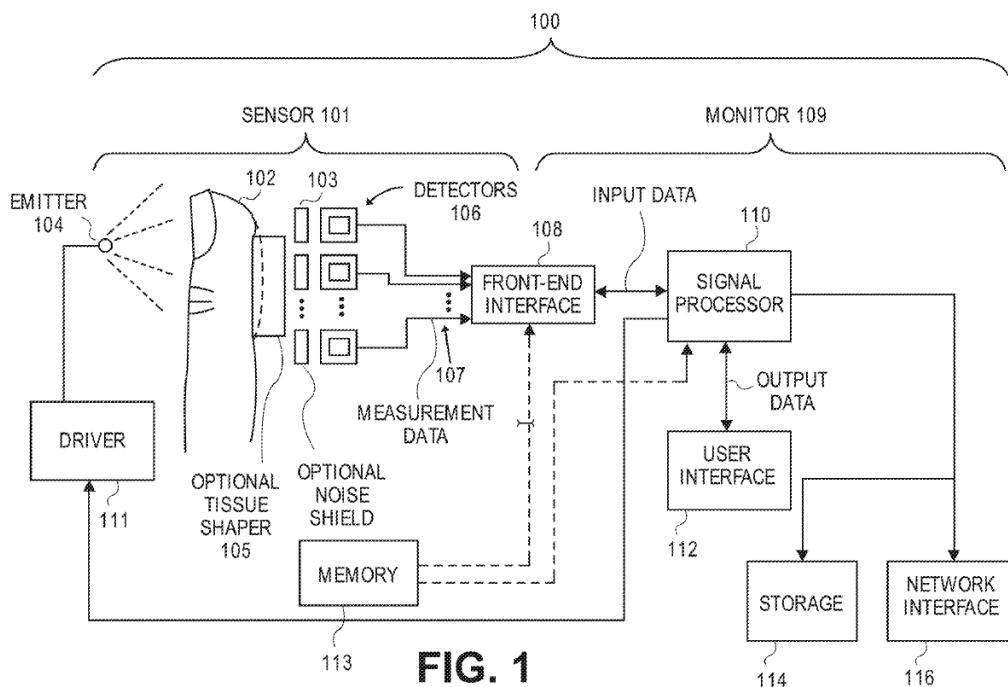


Figure 1 shows data collection system 100, which includes sensor 101 and monitor 109. *Id.* at 11:51–53.

In the embodiment shown in Figure 1, sensor 101 “includes an emitter 104, a tissue shaper 105, a set of detectors 106, and a front-end

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interface 108.” *Id.* at 11:63–65. Emitter 104 can send optical radiation to measurement site 102. *Id.* at 11:65–67. “[E]mitter 104 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like.” *Id.* at 12:1–4. Emitter 104 is driven by driver 111.

*Id.* at 13:55–56. Monitor 109 may control driver 111, which can provide current pulses to emitter 104. *Id.* at 13:56–61.

Detectors 106 may capture and measure light generated by emitter 104 and attenuated or reflected from measurement site 102. *Id.* at 14:7–11. Responsive to the captured or measured light, detectors 106 can produce detector signal 107. *Id.* at 14:11–13. “[D]etectors 106 can be implemented using one or more photodiodes, phototransistors, or the like.” *Id.* at 14:13–14.

The output of detectors 106 is adapted by front end interface 108. *Id.* at 14:31–33. “For example, the front end interface 108 can adapt a signal 107 received from one or more of the detectors 106 into a form that can be processed by the monitor 109.” *Id.* at 14:33–36.

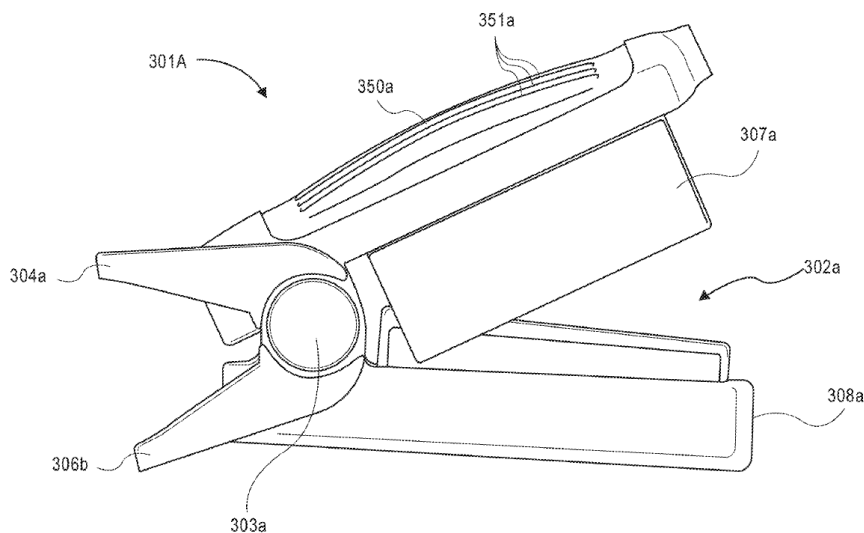
“[M]onitor 109 can include the signal processor 110 and a user interface, such as a display 112,” as well as storage device 114, and network interface 116. *Id.* at 15:21–25. Signal processor 110 may have “processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors 106.” *Id.* at 15:25–29. Signal processor 110 can control sensor 101’s operation with signals, including an emitter control signal provided to driver 111 to control pulses from emitter 104. *Id.* at 15:34–39. “The user interface 112 can provide an output, e.g., on a display, for presentation to a user of the data collection

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system 100.” *Id.* at 15:51–53. “The various software and/or firmware applications can be stored in the storage device 114, which can be executed by the signal processor 110 or another processor of the monitor 109.”

*Id.* at 16:2–5. Network interface 116 may enable monitor 109 to share data and communicate with other devices. *Id.* at 16:5–11.

“[M]ore detailed examples of embodiments of a sensor” appear in Figures 3A through 3C. *Id.* at 18:33–34. Figure 3A is reproduced below.



**FIG. 3A**

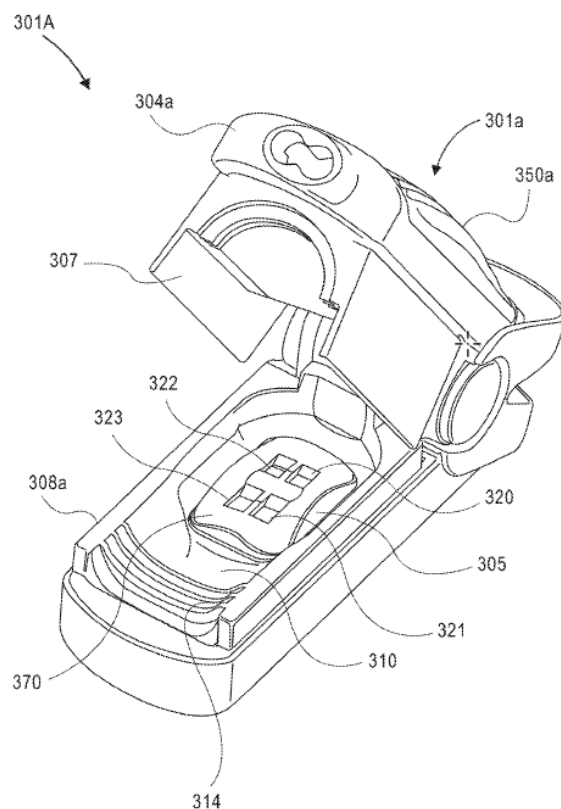
Figure 3A shows sensor 301a, which “is a clothespin-shaped clip sensor that includes an enclosure 302a for receiving a patient’s finger. The enclosure 302a is formed by an upper section or emitter shell 304a, which is pivotally connected with a lower section or detector shell 306a.”<sup>1</sup>

*Id.* at 18:37–42. Another view of sensor 301a appears in Figure 3C, which is reproduced below.

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<sup>1</sup> In this passage, it appears that “detector shell 306a” should read “detector shell 308a.”

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**FIG. 3C**

Figure 3C shows sensor 301a's finger bed 310. *Id.* at 19:7–8.

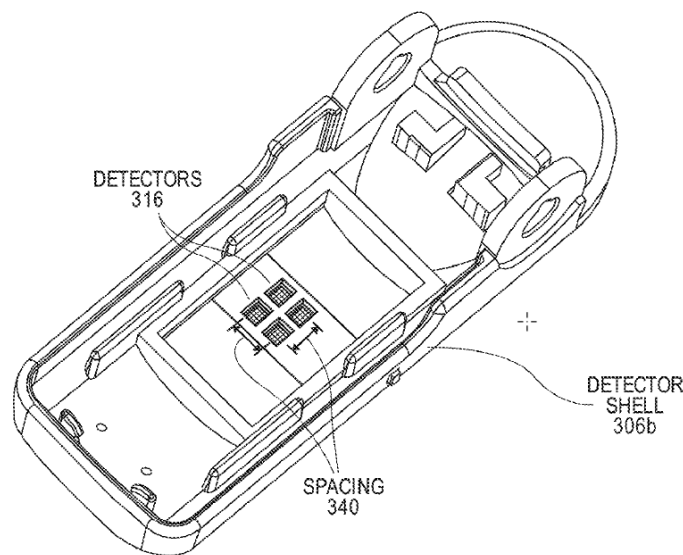
Finger bed 310 may have a generally curved surface suited for receiving flesh, e.g., a human digit. *Id.* at 19:8–10. Ridges 314 on finger bed 310 may help hold a patient's finger to finger bed 310, which can promote accurate spectroscopic analysis. *Id.* at 19:10–17.

Finger bed 310 can also comprise protrusion 305. *Id.* at 19:22–23. Protrusion 305 may be a convex bump. *Id.* at 21:18–19. Protrusion 305 comprises measurement site contact area 370. *Id.* at 19:23–25. Contact area 370 has windows 320, 321, 322, and 323. *Id.* at 19:31–33.

“[W]indows 320, 321, 322, and 323 can be made from materials, such as plastic or glass.” *Id.* at 19:45–46.

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In an embodiment, the location of windows 320, 321, 322, and 323 may mirror the location of photodetectors, allowing light from a measurement site to reach the photodetectors through windows 320, 321, 322, and 323. *Id.* at 19:33–41. Additionally, “[i]n an embodiment, the photodetectors can be positioned within or directly beneath the protrusion.” *Id.* at 20:18–19. The ’648 patent shows this in Figure 3E, which is reproduced below.



**FIG. 3E**

Figure 3E “illustrates a perspective view of an example noninvasive sensor detector shell including example detectors.” *Id.* at 5:56–58.

Specifically, Figure 3E shows detectors 316. *Id.* at 22:28–32. “The detectors 316 can have a predetermined spacing 340 from each other, or a spatial relationship among one another that results in a spatial configuration.” *Id.* at 22:33–35.

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#### D. ILLUSTRATIVE CLAIM

Of the challenged claims, claims 1, 6, 8, and 20 are independent. Each of claims 2–5, 7, 9–19, and 21–30 depends, directly or indirectly, from one of independent claims 1, 6, 8, and 20. Claim 8 is illustrative and is reproduced below with certain reformatting:<sup>2</sup>

1. [8pre] A user-worn device configured to non-invasively determine measurements of physiological parameter of a user, the user-worn device comprising:
  - [8a] a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
  - [8b] a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
  - [8c] four photodiodes;
  - [8d] a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;
  - [8e] a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;
  - [8f] a separate optically transparent window extending across each of the openings;
  - [8g] one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;
  - [8h] a housing; and
  - [8i] a strap configured to position the housing proximate tissue of the user when the device is worn.

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<sup>2</sup> We have added the same labels that Petitioner uses to identify different portions of claim 8. *See* Pet. vi–vii.

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Ex. 1001, 45:45–46:3.

E. EVIDENCE

Petitioner relies on the following evidence:

- (1) U.S. Patent No. 7,620,212 B1, issued Nov. 17, 2009 (“Lumidigm”) (Ex. 1006).
  - (2) Published International Patent Application No. WO 2005/092182 A1, published Oct. 6, 2005 (“Kotanagi”) (Ex. 1007).
  - (3) U.S. Patent No. 9,820,658 B2, issued Nov. 21, 2017 (“Tran”) (Ex. 1008).
  - (4) U.S. Patent No. 9,001,047 B2, issued Apr. 7, 2015 (“Forstall”) (Ex. 1017).
  - (5) U.S. Patent No. 5,952,084, issued Sep. 14, 1999 (“Anderson”) (Ex. 1018).
  - (6) U.S. Patent No. 6,330,468 B1, issued Dec. 11, 2001 (“Scharf”) (Ex. 1025).
  - (7) Declaration of Thomas W. Kenny, Ph.D. (Ex. 1003).
- Patent Owner relies on the declaration of R. James Duckworth, Ph.D. (Ex. 2002).

F. ASSERTED GROUND OF UNPATENTABILITY

Petitioner challenges the patentability of claims 1–30 of the ’648 patent on the following grounds (Pet. 4):

Claims Challenged	35 U.S.C. §	Reference(s)
8, 9	103	Lumidigm, Scharf, Kotanagi
1–7, 10, 12–17, 19, 20–30	103	Lumidigm, Scharf, Kotanagi, Tran



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Claims Challenged	35 U.S.C. §	Reference(s)
11	103	Lumidigm, Scharf, Kotanagi, Tran, Forstall
18	103	Lumidigm, Scharf, Kotanagi, Anderson

## II. ANALYSIS

### A. LEVEL OF ORDINARY SKILL

Petitioner contends that

[a] person of ordinary skill in the art relating to the subject matter of the '648 Patent as of July 3, 2008 ("POSITA") would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. APPLE-1003, ¶¶40-41. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline. *Id.*

Pet. 2. Patent Owner does not dispute Petitioner's description of a person of ordinary skill in the art. *See* Prelim. Resp. 10. For purposes of deciding whether Petitioner has demonstrated a reasonable likelihood of prevailing, we adopt Petitioner's definition of a person of ordinary skill in the art, which we find consistent with the '648 patent and the asserted prior art.

### B. CLAIM CONSTRUCTION

In an *inter partes* review proceeding, a claim of a patent is construed using the same standard used in federal district court, including construing the claim in accordance with the ordinary and customary meaning of the

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claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b) (2020). According to the applicable standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art in question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (citations omitted). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. America Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner argues that “[n]o formal claim constructions are necessary in this proceeding.” Pet. 3. Patent Owner contends we “should give the claim terms their ordinary and customary meaning, consistent with the specification, as a [person of ordinary skill in the art] would understand them.” Prelim. Resp. 10. We do not discern a need to construe any claim language expressly in order to determine whether Petitioner demonstrates a reasonable likelihood of prevailing.

#### C. ALLEGED OBVIOUSNESS OF CLAIMS 8 AND 9 OVER LUMIDIGM, SCHARF, AND KOTANAGI

##### 1. *Overview of Lumidigm*

Lumidigm is titled “Electro-Optical Sensor.” Ex. 1006, code (54).

Lumidigm’s Abstract is reproduced below:

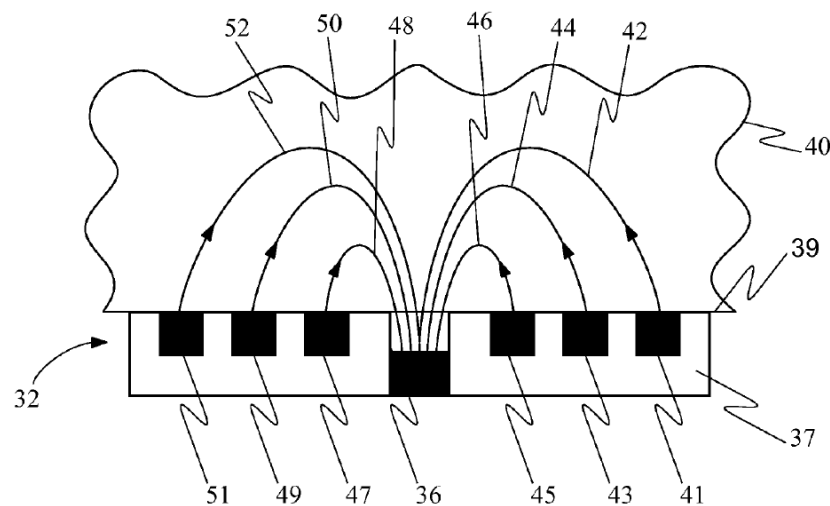
Methods and systems are provided that extend the functionality of electro-optical sensors. A device has a multiple light sources, a light detector, and a processor configured to operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated

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from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector.

*Id.* at code (57).

Lumidigm's Figure 2 is reproduced below:

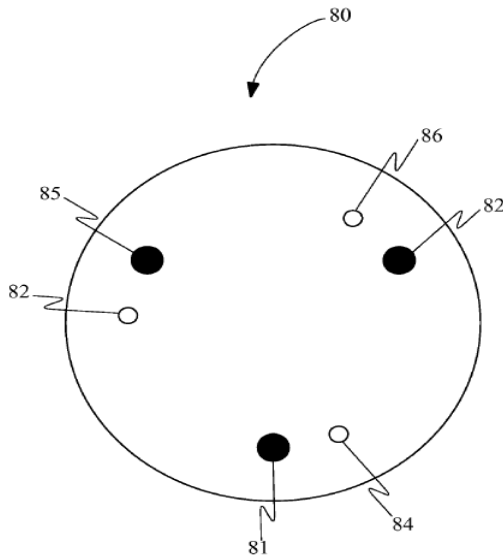


**FIG. 2**

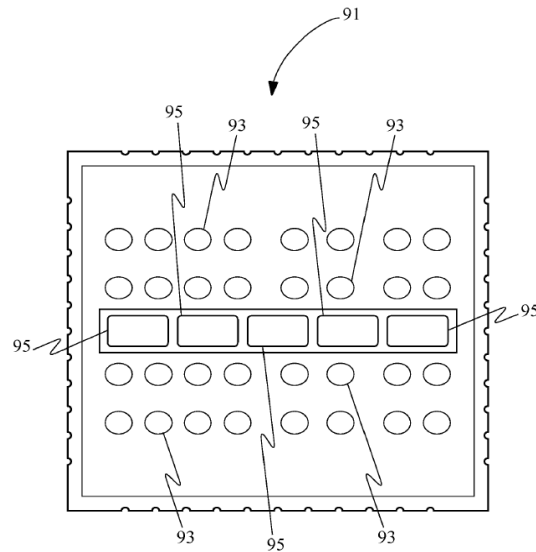
Figure 2 above depicts a “cross-sectional view of a biometric sensor element couple to a tissue surface showing multiple mean optical paths.” *Id.* at 4:45–47. Sensor head 32 includes light sources 41, 43, 45, 47, 49, 51 and detector 36. *Id.* at 7: 5–10. Optical paths 42, 44, 46, 48, 50, 52 show light passing through tissue 40. *Id.* Sensor head 32 is formed of optically opaque material 37.

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Lumidigm's Figures 6 and 7A are reproduced below:



**FIG. 6**



**FIG. 7A**

Figures 6 and 7A above illustrate top-views of biometric sensors according to two embodiments of the invention. *Id.* at 4:60–67. In Figure 6, light sensor 80 includes light sources 82, 84, 86 positioned relative to detectors 81, 83, 85. *Id.* at 9:14–16.<sup>3</sup> In Figure 7A, sensor 91 includes two rows of light sources 93 and one row of detectors 95. *Id.* at 9:27–30.

## 2. Overview of Scharf

Scharf is titled “System Using Green Light to Determine Parameters of a Cardiovascular System.” Ex. 1025, code (54). Scharf describes a reflectance oximeter that uses two green light sources to detect oxygen saturation of hemoglobin in a volume of intravascular blood. *Id.* at 2:39–42.

<sup>3</sup> It would appear that the reference character “82” on the right side of Figure 6 should read “83.”

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Scharf's Figure 3 is reproduced below:

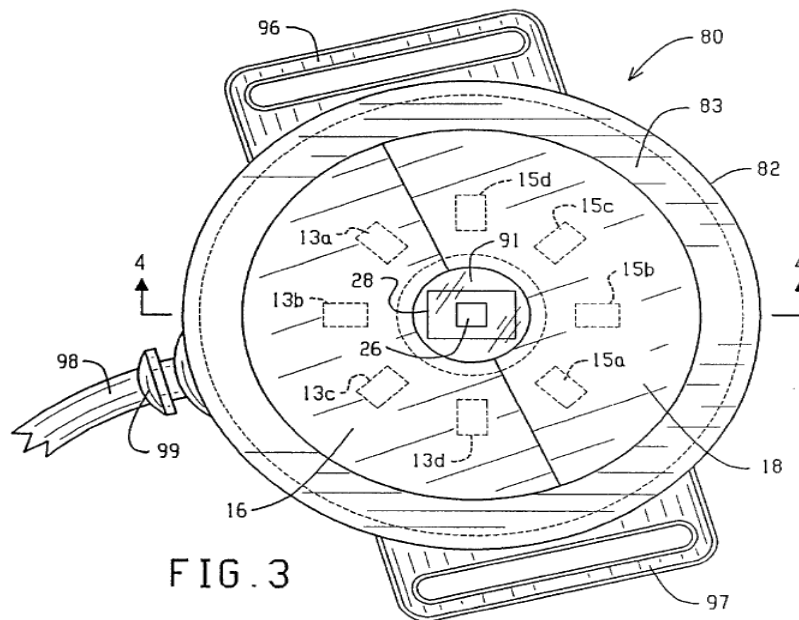


Figure 3 above shows a bottom plan view of an oximeter probe according to an embodiment. *Id.* at 3:40–41. The oximeter probe may include green lights formed of light emitting diodes (LEDs) 13, 15. *Id.* at 4:18–20. Scharf explains that, depending on the particular type of green light sources, green optical filters 16, 18 may be needed. *Id.* at 4:30–34.

### 3. Overview of Kotanagi

Kotanagi is titled “Biological Information Measuring Device.” Ex. 1007, code (54). Kotanagi describes that a biological information measuring device can include a biological sensor including a body and a protrusion formed on the lower surface of the body. *Id.* at code (57). Kotanagi explains that the protrusion can be formed with a “curved surface.” *Id.* ¶ 80.

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4. *Discussion*

A principal feature of independent claim 8 lies in the structure and arrangement of a “protrusion” located over four photodiodes arranged on a user-worn device. In this respect, claim 8 recites:

a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;

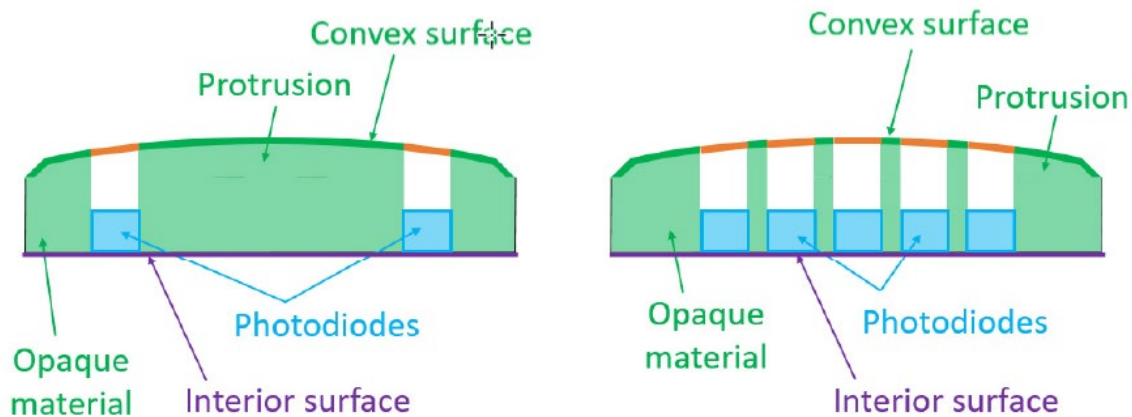
a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes; [and]

a separate optically transparent window extending across each of the openings.

Ex. 1001, 45:57–64. Thus claim 8 requires an at least partially opaque protrusion feature with a convex surface, multiple openings position over multiple photodiodes, and optically transparent windows across the openings.

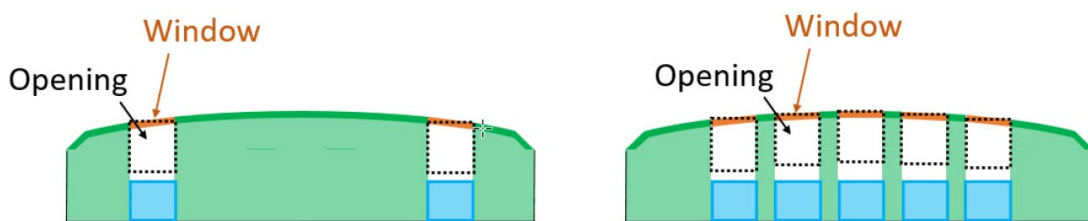
To arrive at the protrusion requirement in the claims, Petitioner presents composite or modified figures that Petitioner contends would have emerged from the teachings of Lumidigm and Kotanagi. Although Lumidigm does not present side views of the optical sensor that is illustrated in its Figures 6 and 7A (reproduced *supra*), Petitioner contends that based on the combined teachings of Lumidigm and Kotanagi, the following figures emerge:

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Pet. 41–42 (citing Ex. 1003 ¶ 125). In Petitioner’s and Dr. Kenny’s view, and as depicted in the modified figure above, the application of Kotanagi’s curved surface to each of Lumidigm’s Figures 6 and 7A results in a “combination device” with a protrusion and “a plurality of openings, one per photodiode, extending through the protrusion and positioned over the photodiodes.” *Id.* at 42 (citing Ex. 1003 ¶ 127) (emphasis omitted). The basis of Petitioner’s proposed ground of unpatentability, however, does not end there.

Additionally, in accounting for the claim language drawn to positioning a separate window across each opening in the convex protrusion, Petitioner alleges that, in light of Scharf’s teachings, the following further modified figures emerge:



*Id.* at 43–44.

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Although it is certainly the case that an obviousness analysis may take into account the inferences and creative steps that a skilled artisan might glean from the teachings of the prior art (*see, e.g., KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)), one must be cognizant that “hindsight is not an available analytical mechanism to show obviousness.” *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1381 (Fed. Cir. 2007) (Newman, J., dissenting). Indeed, “we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.” *See Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017). Without the guidance provided by the claims of the ’648 patent, it is difficult to conclude that Petitioner’s postulation as to a particular structure that results from combining the teachings of Lumidigm, Kotanagi, and Scharf is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for Petitioner’s approach to arriving at the structural requirements of the claims.<sup>4</sup>

At the outset, we share Patent Owner’s view, and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings or windows for multiple detectors. *See, e.g., Prelim. Resp* 28–29; Ex. 2002 ¶ 76. As discussed above, Petitioner attempts to arrive at such structure through a

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<sup>4</sup> Although Petitioner, in a footnote, generally contends that “other examples” of composite figure configurations “could be conceived” so as to render the challenged claims obvious, Petitioner does not provide further assessment or explanation in that regard. *See Pet.* 14 n.5. We find that general contention inadequately supported.



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proposed amalgamation of prior art teachings that must include, for instance, arranging a convex protrusion with multiple openings and separate glass windows over Lumidigm’s optical sensors. In our view, however, Petitioner simply does not explain adequately why such configuration results from the actual teachings of the prior art.

Moreover, in an effort to next account for a convex shape of the protrusions and openings, Petitioner relies on Kotanagi’s curved protrusion as providing, for instance, “better contact” and be “more comfortable” for a user of Lumidigm’s detector. *See, e.g.*, Pet. 29–30. Yet, consistent with the arguments advanced by Patent Owner and Dr. Duckworth, we are not satisfied that Petitioner adequately explains why a skilled artisan would have expected that such benefits would apply to the convoluted combination of modifications Petitioner proposes to arrive at the claimed invention. *See, e.g.*, Prelim. Resp. 43–52; Ex. 2002 ¶¶ 163–175. Nor has Petitioner explained adequately why a skilled artisan would have assessed that Petitioner’s reasoning applies to a protrusion configured to have specific characteristics, e.g., at least partly having opaque material and having multiple distinct openings, that are unaffiliated with concerns of contact or comfort. *See, e.g.*, Prelim. Resp. 43–52; Ex. 2002 ¶¶ 163–175.

Further still, we share Patent Owner’s skepticism (*see, e.g.*, Prelim. Resp. 63–67) that Petitioner’s reliance on Scharf’s teachings justifies Petitioner’s theory that separate glass coverings or windows would be placed over different openings within a convex protrusion. *See, e.g.*, Pet. 32–33. Although Petitioner expresses that “glass covers” generally are known in the art, in our view, Petitioner does not explain adequately why the particular teachings of Scharf on which Petitioner relies give rise to the specific

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window configuration required by the noted claims. *See id.* Dr.

Duckworth’s testimony supports Patent Owner’s argument that Scharf’s teachings applied to a combination of Lumidigm and Kotanagi do not convey reasonably to a skilled artisan the positioning of windows over the openings of a convex protrusion in the manner urged by Petitioner. *See, e.g.,* Ex. 2002 ¶¶ 179–185.

After consideration of the record before us, we find questionable Petitioner’s and Dr. Kenny’s assessment and reasoning as to what a skilled artisan would have understood from the teachings of Lumidigm, Scharf, and Kotanagi as proposed by Petitioner here. We find persuasive Patent Owner’s arguments that Petitioner’s and Dr. Kenny’s assessments are grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art. *See, e.g.,* Prelim. Resp. 26–28. Dr. Duckworth’s testimony that one of ordinary skill in the art would not have combined the teachings of the prior art in the manner advocated by Petitioner further supports Patent Owner’s arguments. *See, e.g.,* Ex. 2002 ¶¶ 163–175, 179–185.

Based on the record here, we conclude Petitioner has not shown a reasonable likelihood of demonstrating obviousness of either claim 8 or 9 in view of Lumidigm, Scharf, and Kotanagi.

D. ALLEGED OBVIOUSNESS OF CLAIMS 1–7, 10, 12–17, 19, AND  
20–30 OVER LUMIDIGM, SCHARF, KOTANAGI, AND TRAN

1. *Overview of Tran*

Tran discusses patient monitoring in connection with Figure 1. Ex. 1008, 8:42. Figure 1 is reproduced below.

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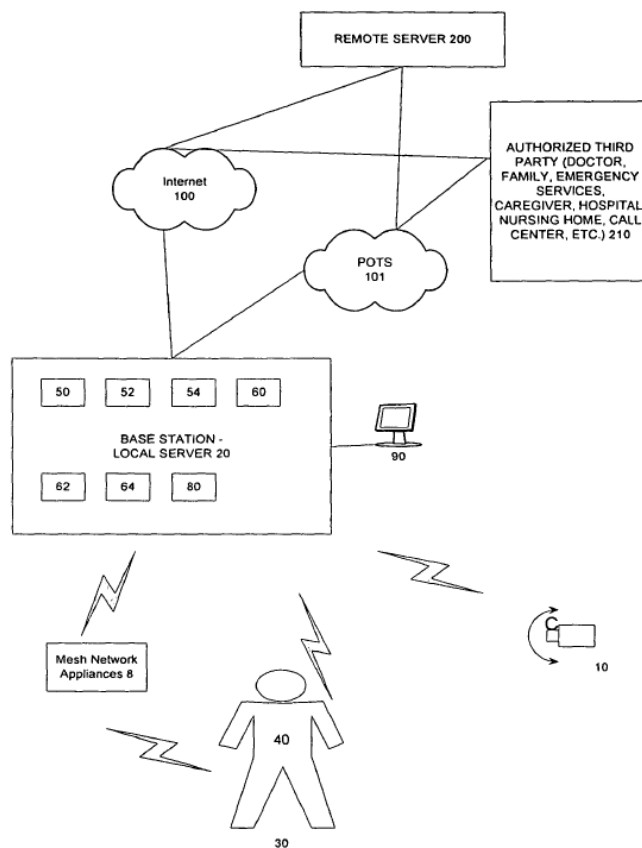


FIG. 1

Figure 1 shows “an exemplary system for monitoring a person.” *Id.* at 8:7–8.

The system may include appliances 8, which can be one of multiple portable physiological transducer, such as a blood pressure monitor, heart rate monitor, weight scale, thermometer, spirometer, single or multiple lead electrocardiograph (ECG), a pulse oximeter, a body fat monitor, a cholesterol monitor a signal from a medicine cabinet, a signal from a drug container, a signal from a commonly used appliance such as a refrigerator/stove/oven/washer, or a signal from an exercise machine such as a heart rate.

*Id.* at 8:49–58.

Tran explains that “one appliance is a patient monitoring device that can be worn by a patient.” *Id.* at 8:59–60. Tran adds that patient 30 “may

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wear one or more wearable patient monitoring appliances such as wrist-watches or clip on devices or electronic jewelry to monitor the patient.” *Id.* at 9:66–10:1. “One wearable appliance such as a wrist-watch includes sensors 40, for example devices for sensing ECG, EKG, blood pressure, sugar level, among others.” *Id.* at 10:1–4. Tran discusses an example in connection with Figure 6A. Figure 6A is reproduced below.

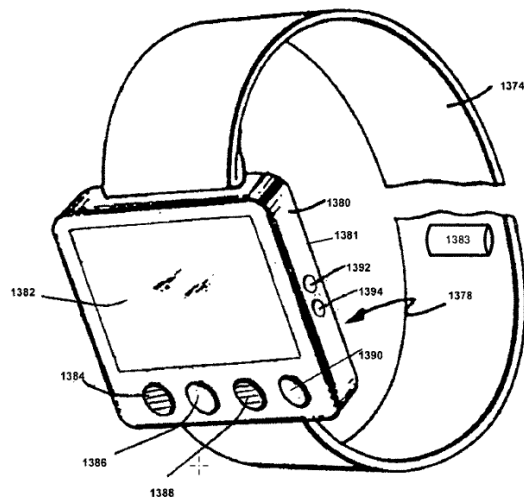


FIG. 6A

Figure 6A “shows an exemplary wrist-watch based assistance device.” *Id.* at 8:16–17. The device comprises a wrist-watch sized case 1380 attached to a wrist band 1374. *Id.* at 46:5–6. “The housing 1380 contains the processor and associated peripherals to provide the human-machine interface.” *Id.* at 49:11–13. The front section of housing 1380 includes display 1382, speaker 1384, push-button switch 1386, microphone 1388, and push-button switch 1390. *Id.* at 49:13–17.

## 2. Discussion

Petitioner’s challenge of claims 1–5, 6, 7, 10, 12–17, 19, and 20–30 based on Lumidigm, Scharf, Kotanagi, and Tran builds from its challenge of

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independent claim 8 based on Lumidigm, Scharf, and Kotanagi.<sup>5</sup>

Pet. 49–87. When addressing the limitations of independent claims 1, 6, and 20, the Petition generally refers back to its treatment of the limitations of independent claim 8 based on Lumidigm, Scharf, and Kotanagi. *E.g.*, Pet. 57–65, 70–73, 81–82. Petitioner adds arguments and evidence regarding Tran to address certain limitations not present in independent claim 8, such as independent claim 1’s requirement for “one or more processors configured to . . . determine measurements of oxygen saturation of the user.” Ex. 1001, 44:63–65; Pet. 65. The evidence and arguments Petitioner adds to address claims 1–5, 6, 7, 10, 12–17, 19, and 20–30 do not cure the deficiencies, discussed above in Section II.C.4, in Petitioner’s assertions that claims 8 and 9 would have been obvious over Lumidigm, Scharf, and Kotanagi. Petitioner has not demonstrated a reasonable likelihood of establishing that any of claims 1–5, 6, 7, 10, 12–17, 19, and 20–30 would have been obvious over Lumidigm, Scharf, Kotanagi, and Tran.

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<sup>5</sup> In contrast to page 4 of the Petition, Page 49 of the Petition includes claim 18 among those that Petitioner contends is allegedly obvious over Lumidigm, Scharf, Kotanagi, and Tran. But the section of the Petition discussing the details of the challenge based on Lumidigm, Scharf, Kotanagi, and Tran does not further discuss claim 18. *See* Pet. 49–87. Accordingly, the statement on page 49 of the Petition that claim 18 would have been obvious over Lumidigm, Scharf, Kotanagi, and Tran appears to be a typographical error.

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E. ALLEGED OBVIOUSNESS OF CLAIM 11 OVER LUMIDIGM, SCHARF, KOTANAGI, TRAN, AND FORSTALL

1. *Overview of Forstall*

Forstall discloses a portable multifunction device that, in some embodiments, “has a touch-sensitive display (also known as a ‘touch screen’) with a graphical user interface (GUI), one or more processors, memory and one or more modules, programs, or sets of instructions stored in the memory for performing multiple functions.” Ex. 1017, 2:36–43.

Forstall’s Figure 2 is reproduced below.

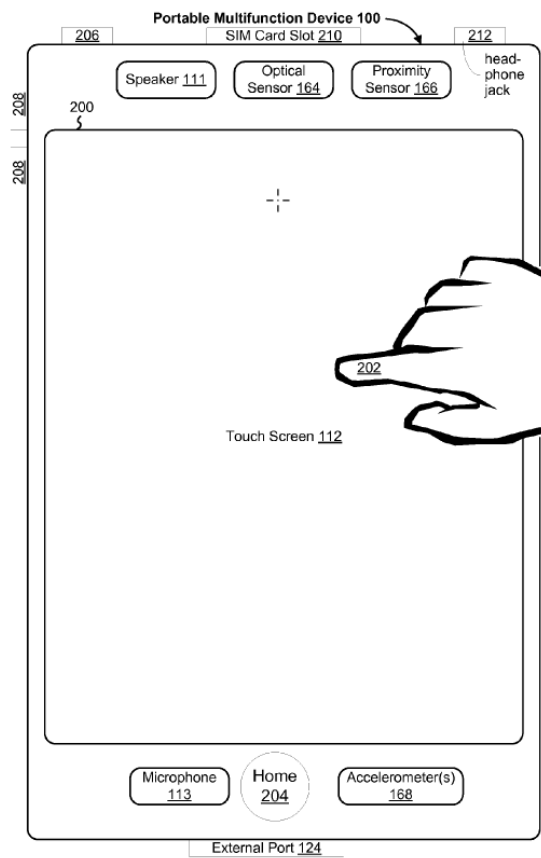


Figure 2

Figure 2 “illustrates a portable multifunction device having a touch screen in accordance with some embodiments.” *Id.* at 4:7–8.

In particular, Figure 2 shows portable multifunction device 100, which includes touch screen 112. *Id.* at 14:66–15:1. Inside user interface

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200, touch screen 112 may present one or more graphics. *Id.* at 15:1–2.

“[A] user may select one or more of the graphics by making contact or touching the graphics, for example, with one or more fingers 202.” *Id.* at 15:3–5. Forstall explains that

[a] graphical user interface one a portable multifunction device with a rectangular touch screen display with a portrait view and a landscape view comprises a first mode of an application that is displayed in the portrait view and a second mode of the application that is displayed in the landscape view.

*Id.* at 18:59–64. Forstall adds that mode changes based on device orientation make the device easier to use because the user does not have to navigate through one or more display screens to get to a desired second mode or remember how to perform such navigation. Rather, the user changes the orientation of the device (e.g., from vertical or portrait to horizontal or landscape) to transition an application to a corresponding second mode.

*Id.* at 19:4–10.

## 2. Discussion

Claim 11 depends indirectly from independent claim 8. Ex. 1001, 46:4–12. Petitioner’s challenge of claim 11 based on Lumidigm, Scharf, Kotanagi, Tran, and Forstall cites Forstall because it allegedly “discloses a portable device with a touch screen user interface with orientation capability.” Pet. 87. Based on this and arguments that it would have been obvious to add Forstall’s disclosures to those of Lumidigm, Scharf, Kotanagi, and Tran, Petitioner argues that “[t]he ***orientation of the user interface*** of the touch screen of the combination device (e.g., orientation from vertical/portrait to horizontal/landscape)) is dependent on ***user input*** (e.g., the user changes the orientation of the device).” *Id.* at 89. Petitioner’s arguments and evidence regarding the alleged obviousness of claim 11 over

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Lumidigm, Scharf, Kotanagi, Tran, and Forstall do not cure the deficiencies, discussed above in Section II.C.4, in Petitioner’s assertions that independent claim 8 would have been obvious over Lumidigm, Scharf, and Kotanagi. Petitioner has not demonstrated a reasonable likelihood of establishing that claim 11 would have been obvious over Lumidigm, Scharf, Kotanagi, Tran, and Forstall.

F. ALLEGED OBVIOUSNESS OF CLAIM 18 OVER LUMIDIGM, SCHARF, KOTANAGI, AND ANDERSON

1. *Overview of Anderson*

Anderson relates to “transparent substrates, in particular glass substrates, which are provided with coatings composed of one or more thin films . . . designed to give specific properties to the substrates which bear them, for example, thermal, optical, or electrical properties.” Ex. 1018, 1:5–10. Anderson explains that an “anti-reflection coating” works to decrease a substrate’s light reflection factor, thereby “increasing its light transmission factor.” *Id.* at 1:22–28. This increases the visibility of objects behind the substrate. *Id.* at 1:28–30. An anti-reflection coating may be a stack of certain materials. *Id.* at 5:1–6. Additionally, including a conductive material film in the stack can provide an anti-static function. *Id.* at 5:32–38.

2. *Discussion*

Claim 18 recites “[t]he user-worn device of claim 8, wherein the windows comprise a conductive material.” Ex. 1001, 46:29–30. Petitioner’s challenge of claim 18 based on Lumidigm, Scharf, Kotanagi, and Anderson cites Anderson because it allegedly discloses a coating with “‘a film of a conductive material’ *e.g.*, ‘a material of the doped metal oxide type, such as tin-doped indium oxide ITO.’” Pet. 90. Based on this and arguments that it



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would have been obvious to add Anderson’s disclosures to those of Lumidigm, Scharf, and Kotanagi, Petitioner argues that “[i]n the combination, *the windows include* an anti-reflection coating containing a ‘*conductive material*,’ such as ‘**a material of the doped metal oxide type, such as tin-doped indium oxide ITO**,’ as taught by Anderson, on at least one surface.” *Id.* at 92. Petitioner’s arguments and evidence regarding the alleged obviousness of claim 18 over Lumidigm, Scharf, Kotanagi, and Anderson do not cure the deficiencies, discussed above in Section II.C.4, in Petitioner’s assertions that independent claim 8 would have been obvious over Lumidigm, Scharf, and Kotanagi. Petitioner has not demonstrated a reasonable likelihood of establishing that claim 18 would have been obvious over Lumidigm, Scharf, Kotanagi, and Anderson.

### III. CONCLUSION

Because we determine that the information presented in the record does not establish there is a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim of the patent ’648 patent, we do not institute an *inter partes* review.

### IV. ORDER

For the reasons given, it is:

ORDERED that the Petition is *denied* as to all challenged claims of the ’648 patent and no trial is instituted.

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Patent 10,945,648 B2

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# APPENDIX B

[Trials@uspto.gov](mailto:Trials@uspto.gov)  
571-272-7822

Paper 16  
Entered: January 24, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APPLE INC.,  
Petitioner,

v.

MASIMO CORPORATION,  
Patent Owner.

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IPR2022-01272  
Patent 10,912,501 B2

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Before JOSIAH C. COCKS, NEIL T. POWELL, and  
JAMES A. TARTAL, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

DECISION  
Denying Institution of *Inter Partes* Review  
35 U.S.C. § 314

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Patent 10,912,501 B2

## I. INTRODUCTION

Petitioner Apple Inc. filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1–30 (“the challenged claims”) of U.S. Patent No. 10,912,501 B1 (Ex. 1001, “the ’501 patent”).<sup>1</sup> Patent Owner Masimo Corporation filed a Preliminary Response (Paper 11, “Prelim. Resp.”). We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”).

Having considered the arguments and evidence presented in the Petition, for the reasons described below, we do not institute *inter partes* review.

### A. Related Matters

The parties state that the ’501 patent is the subject of *Masimo Corporation, et al. v. Apple Inc.*, ITC Inv No. 337-TA-1276. Pet. 1; Paper 5, 1. Patent Owner also identifies numerous additional patent applications, patents, and *inter partes* review proceedings as related to the ’501 patent. Paper 5, 1–3.

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<sup>1</sup> Petitioner additionally filed another Petition (IPR2022-01271) that also challenges claims 1–30 of the ’501 patent.

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*B. The '501 Patent*

The '501 patent is titled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User.” Ex. 1001, code (54). The '501 patent summarizes its disclosure as follows:

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

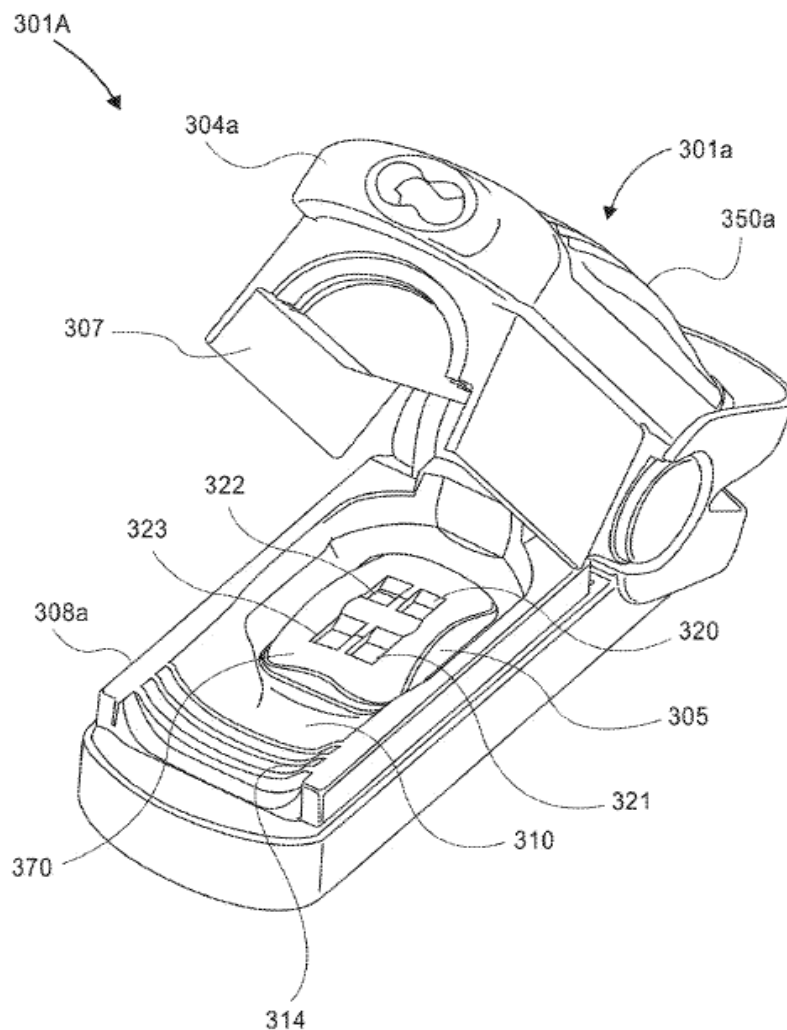
In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the noninvasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

*Id.* at 2:38–60.

The '501 patent describes that “[i]n noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.” *Id.* at 2:30–34.

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Figure 3C of the '501 patent is reproduced below:



**FIG. 3C**

Figure 3C above illustrates an example sensor including a finger bed protrusion according to an embodiment of the disclosure. *Id.* at 5:52–55. Sensor 301a includes detector shell 306a (not numbered in Figure 3c) with lower area 308a that can “include absorbing opaque material . . . to reduce ambient light entering the sensor 301a.” *Id.* at 19:4–12. Finger bed 310 includes convex protrusion 305 with openings or windows 320, 321, 322, and 322 that “mirror specific detector placement layouts such that light can impinge through the protrusion 305 onto” photodetectors (not illustrated in

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Figure 3C) that may be positioned beneath the protrusion. *Id.* at 19:42–48; 20:25–34.

### *C. Challenged Claims*

Petitioner challenges claims 1–30 of the '501 patent. Claims 1, 19, and 26 are independent claims. Claim 1 is representative and is reproduced below:

1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:

at least three light emitting diodes (LEDs);

at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;

a protrusion arranged over the interior surface, the protrusion comprising a convex surface and a plurality of openings extending through the protrusion and positioned over the three photodiodes, the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion; and

one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.

Ex. 1001, 45:2–19.



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*D. Alleged Grounds of Unpatentability*

Petitioner asserts the following grounds of unpatentability:

<b>Claim(s) Challenged</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>
1, 2, 5, 7, 8, 11–18, 19, 22, 25	103	Lumidigm, <sup>2</sup> Scharf, <sup>3</sup> Kotanagi <sup>4</sup>
3, 4, 6, 9, 10, 20, 21, 23, 24, 26–30	103	Lumidigm, Scharf, Kotanagi, Tran <sup>5</sup>

Pet. 1. In addition to the references listed above, Petitioner relies on the Declaration of Dr. Thomas W. Kenny (Ex. 1003).

**II. ANALYSIS**

*A. Principles of Law*

A petition must show how the construed claims are unpatentable under the statutory grounds it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner bears the burden of demonstrating a reasonable likelihood that it would prevail with respect to at least one challenged claim for a petition to be granted. 35 U.S.C. § 314(a).

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a

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<sup>2</sup> U.S. Patent No. 7,620,212 B1 issued Nov. 17, 2009 (“Lumidigm,” Ex. 1006). Although Jeffrey G. Allen is listed as the first named inventor of the U.S. Patent No. 7,620,212 B2, Lumidigm, Inc. is listed as the Assignee. *See* Ex. 1006, code (73). Like the parties in their briefings in this proceeding, we refer to the noted patent as “Lumidigm.”

<sup>3</sup> U.S. Patent No. 6,330,468 B1 issued Dec. 11, 2001 (“Scharf,” Ex. 1025).

<sup>4</sup> PCT Application No. WO 2005/092182 A1 published Oct. 6, 2005 (“Kotanagi,” Ex. 1007 (English translation)).

<sup>5</sup> U.S. Patent No. 9,820,658 B2 issued Nov. 21, 2017 (“Tran,” Ex. 1008).

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person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective indicia of non-obviousness (i.e., secondary considerations). *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

At this preliminary stage, we determine whether the information presented shows a reasonable likelihood that Petitioner would prevail in establishing that at least one of the challenged claims would have been obvious over the proposed prior art. We analyze the asserted grounds with the above-noted principles in mind.

### *B. Level of Ordinary Skill in the Art*

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the

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technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends the following in connection with a person of ordinary skill in the art:

A person of ordinary skill in the art relating to the subject matter of the '501 Patent as of July 3, 2008 ("POSITA") would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Pet. 4 (citing Ex. 1003 ¶¶ 40–41).

Patent Owner does not dispute this proposed level of skill. Prelim. Resp. 10.

For purposes of this Decision, we adopt Petitioner's proposal as reasonable and consistent with the prior art and the '501 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art may reflect an appropriate level of skill in the art).

### *C. Claim Construction*

We construe claims in the same manner used in a civil action under 35 U.S.C. § 282(b) "including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent."

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37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim language as it would have been understood by one of ordinary skill in the art in light of the specification. *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279–80 (Fed. Cir. 2017). Thus, we give claim terms their ordinary and customary meaning as understood by an ordinarily skilled artisan. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Neither party offers any express construction for any claim term. *See* Pet. 4; Prelim. Resp. 9. We determine that all claim terms should be given their ordinary and customary meaning and that it is unnecessary to make that meaning explicit for any term.

#### *D. Grounds Based on Lumidigm, Scharf, and Kotanagi*

Petitioner contends that all of the challenged claims (i.e., claims 1–30) are rendered obvious based, in whole or in part, on the combined teachings of Lumidigm, Scharf, and Kotanagi.<sup>6</sup> As expressed throughout its Preliminary Response, Patent Owner does not agree.

##### *1. Overview of Lumidigm*

Lumidigm is titled “Electro-Optical Sensor.” Ex. 1006, code (54). Lumidigm’s Abstract is reproduced below:

Methods and systems are provided that extend the functionality of electro-optical sensors. A device has a multiple

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<sup>6</sup> For claims 3, 4, 6, 9, 10, 20, 21, 23, 24, and 26–30, Petitioner additionally relies on Tran.

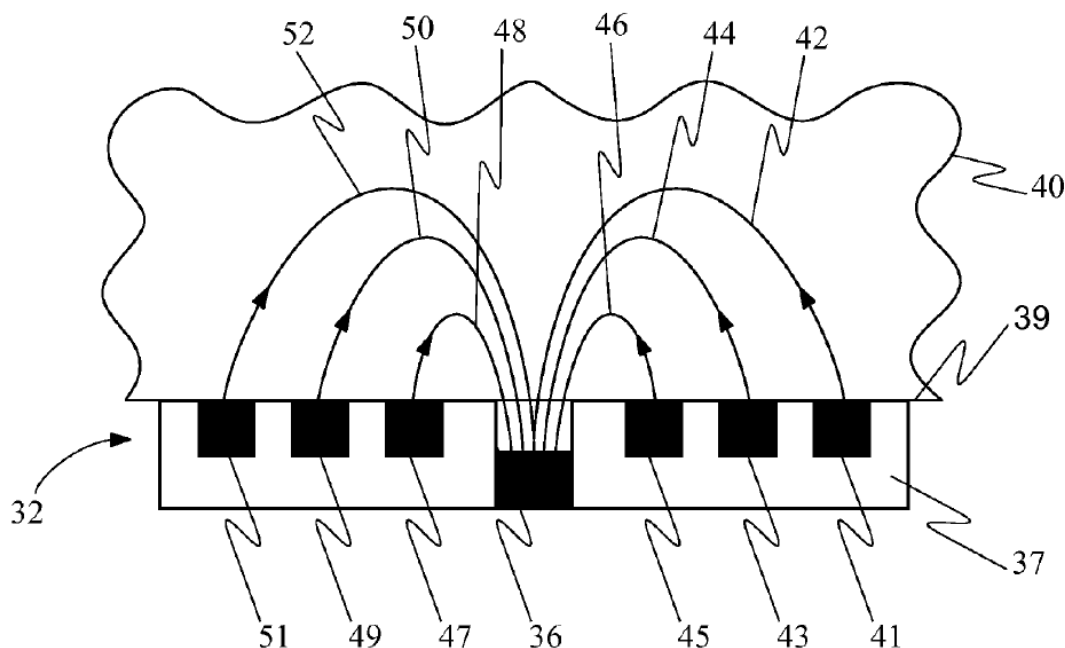
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light sources, a light detector, and a processor configured to operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector.

*Id.* at code (57).

Lumidigm's Figure 2 is reproduced below:



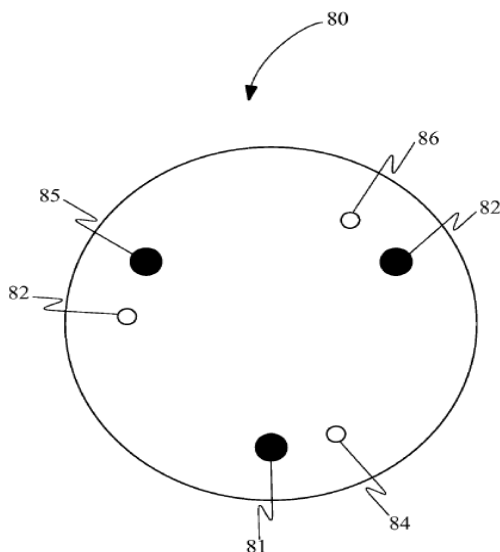
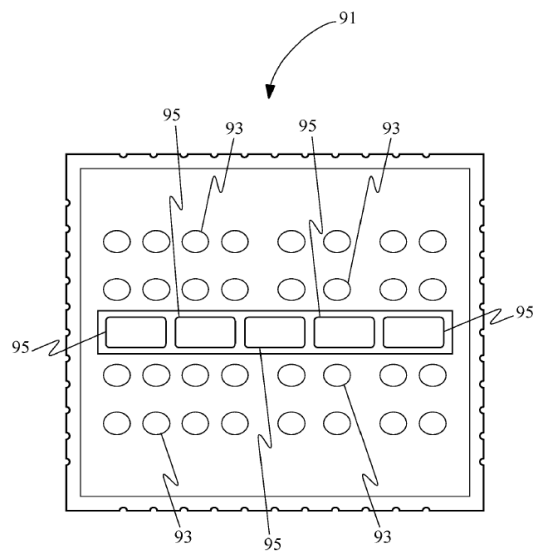
**FIG. 2**

Figure 2 above depicts a “cross-sectional view of a biometric sensor element couple to a tissue surface showing multiple mean optical paths.” *Id.* at 4:45–47. Sensor head 32 includes light sources 41, 43, 45, 47, 49, 51 and detector 36. *Id.* at 7: 5–10. Optical paths 42, 44, 46, 48, 50, 52 show light passing through tissue 40. *Id.* Sensor head 32 is formed of optically opaque material 37.

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Lumidigm's Figures 6 and 7A are reproduced below:

**FIG. 6****FIG. 7A**

Figures 6 and 7A above illustrate top-views of biometric sensors according to two embodiments of the invention. *Id.* at 4:60–67. In Figure 6, light sensor 80 includes light sources 82, 84, 86 positioned relative to detectors 81, 83, 85. *Id.* at 9:14–16.<sup>7</sup> In Figure 7A, sensor 91 includes two rows of light sources 93 and one row of detectors 95. *Id.* at 9:27–30.

## 2. Overview of Scharf

Scharf is titled “System Using Green Light to Determine Parameters of a Cardiovascular System.” Ex. 1025, code (54). Scharf describes a reflectance oximeter that uses two green light sources to detect oxygen saturation of hemoglobin in a volume of intravascular blood. *Id.* at 2:39–42.

<sup>7</sup> It would appear that the reference character “82” on the right side of Figure 6 should read “83.”

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Scharf's Figure 3 is reproduced below:

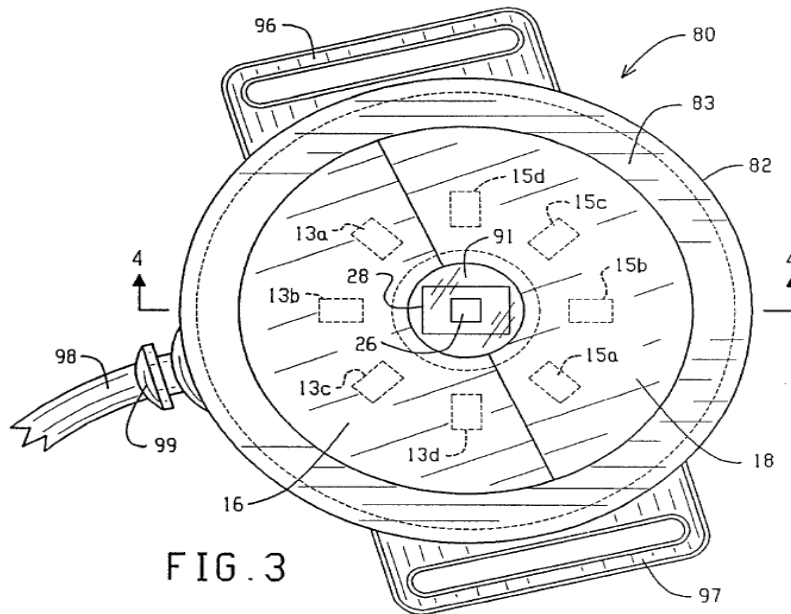


Figure 3 above shows a bottom plan view of an oximeter probe according to an embodiment. *Id.* at 3:40–41. The oximeter probe may include green lights formed of light emitting diodes (LEDs) 13, 15. *Id.* at 4:18–20. Scharf explains that, depending on the particular type of green light sources, green optical filters 16, 18 may be needed. *Id.* at 4:30–34.

### 3. Overview of Kotanagi

Kotanagi is titled “Biological Information Measuring Device.”

Ex. 1007, code (54). Kotanagi describes that a biological information measuring device can include a biological sensor including a body and a protrusion formed on the lower surface of the body. *Id.* at code (57).

Kotanagi explains that the protrusion can be formed with a “curved surface.” *Id.* ¶ 80.

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#### 4. Discussion

A principal feature of each of the independent claims of the '501 patent lies in the structure and arrangement of a “protrusion” located over at least three photodiodes arranged on an interior surface of a user-worn device. In particular, in claim 1 that feature reads as follows:

a protrusion arranged over the interior surface, the protrusion comprising a convex surface and a plurality of openings extending through the protrusion and positioned over the three photodiodes, the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion[.]

Ex. 1001, 45:9–16.

Thus, in claim 1, the protrusion feature requires a convex surface and multiple openings with opaque lateral surfaces that are positioned over multiple photodiodes in a configuration “to avoid light piping.” “Light piping” is understood to be an undesirable condition in which “light bypasses” the measurement site, e.g., human tissue, without being attenuated by that tissue. *See* Ex. 1001, 22:48–50; *see also* Prelim. Resp. 6–7 (description of light piping). Independent claims 19 and 26 include similar requirements of such a protrusion.<sup>8</sup>

To arrive at the protrusion requirement in the claims, Petitioner presents composite or modified figures that Petitioner contends would have emerged from the teachings of Lumidigm and Kotanagi. Although Lumidigm does not present side views of the optical sensor that is illustrated

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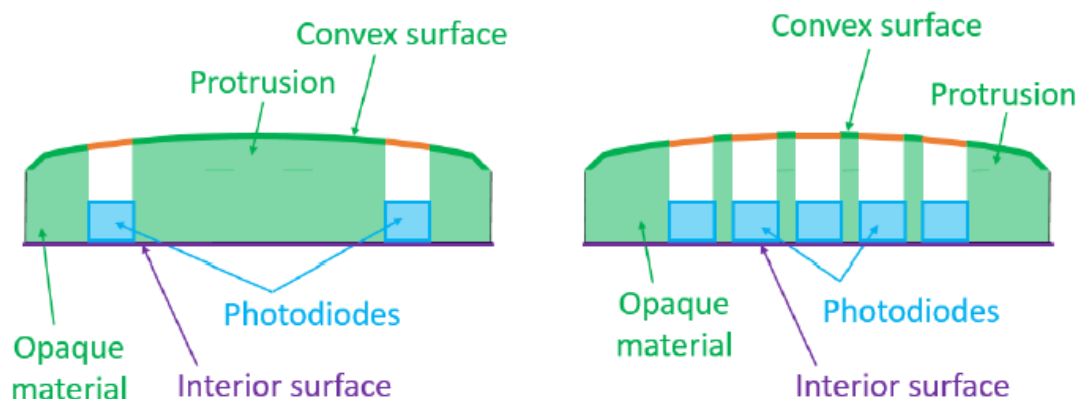
<sup>8</sup> In claim 19, in lieu of “a plurality of openings,” there is a requirement of “a separate window” associated with each photodiode and configured to “reduce an amount of light reaching the photodiodes without being attenuated by the tissue.” Ex. 1001, 46:42–49.



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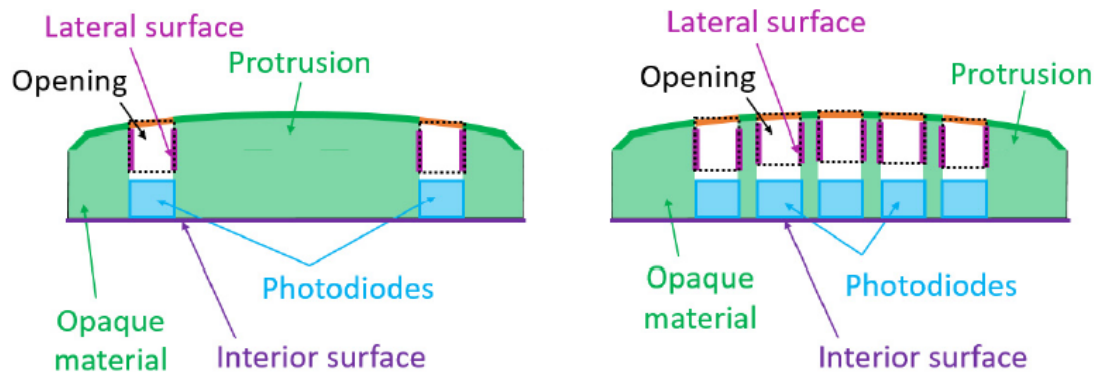
in its Figures 6 and 7A (reproduced *supra*), Petitioner contends that based on the combined teachings of Lumidigm and Kotanagi, the following figures emerge:



Pet. 37–38 (citing Ex. 1003 ¶ 112). In Petitioner’s and Dr. Kenny’s view, and as depicted in the modified figure above, the application of Kotanagi’s curved surface to each of Lumidigm’s Figures 6 and 7A results in a “combination device” with a protrusion and “a plurality of openings, one per photodiode, extending through the protrusion and positioned over the photodiodes.” *Id.* at 38 (citing Ex. 1003 ¶ 114) (emphasis omitted). The basis of Petitioner’s proposed ground of unpatentability, however, does not end there.

To account for the requirement, for instance, in claim 1 pertaining to an opaque surface that is associated with each opening, Petitioner offers the following additional “[c]omposite figures”:

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Pet. 39. According to Petitioner, the combined teachings of Lumidigm and Kotanagi additionally would be configured to include distinct opaque lateral surfaces (shown in purple in the composite figures above), that extend along some portion of the recessed openings over each photodiode that are said to be created and present a structure that “avoids light piping.” *Id.* at 40 (emphasis omitted).

Furthermore, we note that Petitioner’s combination figures include what appears to be distinct structures colored in orange that reside above the proposed recessed openings in the depicted protrusion. In connection with claims of the ’501 patent requiring that “glass covers each of the openings” or “separate windows associated” with each of the photodiodes (e.g., claims 2 and 19), Petitioner contends that in view of Scharf’s teachings, those requirements are satisfied based on the structure based on the illustrated orange portion in the combination figures. *See, e.g.*, Pet. 43–44, 68–69

Although it is certainly the case that an obviousness analysis may take into account the inferences and creative steps that a skilled artisan might glean from the teachings of the prior art (*see, e.g., KSR*, 550 U.S. at 418), one must be cognizant that “hindsight is not an available analytical mechanism to show obviousness.” *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1381 (Fed. Cir. 2007) (Newman, J., dissenting). Indeed, “we

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cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.” *See Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017).

Without the guidance provided by the claims of the ’501 patent, it is difficult to conclude that Petitioner’s postulation as to a particular structure that results from combining the teachings of Lumidigm, Kotanagi, and Scharf is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for Petitioner’s approach to arriving at the structural requirements of the claims.<sup>9</sup>

At the outset, we share Patent Owner’s view, and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings or windows for multiple detectors. *See, e.g.*, Prelim. Resp 28–29; Ex. 2002 ¶ 76. As discussed above, Petitioner attempts to arrive at such structure through a proposed amalgamation of prior art teachings that must include, for instance, arranging a convex protrusion with multiple openings or separate glass windows over Lumidigm’s optical sensors. In our view, however, Petitioner simply does not explain adequately why such configuration results from the actual teachings of the prior art.

Moreover, in an effort to next account for a convex shape of the protrusions and openings, Petitioner relies on Kotanagi’s curved protrusion

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<sup>9</sup> Although Petitioner, in a footnote, generally contends that “other examples” of composite figure configurations “could be conceived” so as to render the challenged claims obvious, Petitioner does not provide further assessment or explanation in that regard. *See* Pet. 14 n.5. We find that general contention inadequately supported.

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as providing, for instance, “better contact” and be “more comfortable” for a user of Lumidigm’s detector. *See, e.g.*, Pet. 24–25. Yet, consistent with the arguments advanced by Patent Owner and Dr. Duckworth, we are not satisfied that Petitioner adequately explains why a skilled artisan would have expected that such benefits would apply to the convoluted combination of modifications Petitioner proposes to arrive at the claimed invention. *See, e.g.*, Prelim. Resp. 41–50; Ex. 2002 ¶¶ 150–162. Nor has Petitioner explained adequately why a skilled artisan would have assessed that Petitioner’s reasoning applies to a protrusion configured to have specific characteristics, e.g., multiple distinct openings and opaque lateral surfaces, intended to provide a particular function, i.e., reduction of light piping, that is unaffiliated with concerns of contact or comfort. *See, e.g.*, Prelim. Resp. 41–50; Ex. 2002 ¶¶ 150–162.

Further still, we share Patent Owner’s skepticism (*see, e.g.*, Prelim. Resp. 68–72) that Petitioner’s reliance on Scharf’s teachings justifies Petitioner’s theory that separate glass coverings or windows (e.g., as required by claims 2 and 19) would be placed over different openings within a convex protrusion. *See, e.g.*, Pet. 27–28. Although Petitioner expresses that “glass covers” generally are known in the art, in our view, Petitioner does not explain adequately why the particular teachings of Scharf on which Petitioner relies give rise to the specific window configuration required by the noted claims. *See id.* Dr. Duckworth’s testimony supports Patent Owner’s argument that Scharf’s teachings applied to a combination of Lumidigm and Kotanagi do not convey reasonably to a skilled artisan the positioning of windows over the openings of a convex protrusion in the manner urged by Petitioner. *See, e.g.*, Ex. 2002 ¶¶ 171–178. Moreover, left wanting from Petitioner’s theories is why a person of ordinary skill in the art

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would seek to apply Scharf's teachings as to a sensor face incorporating particular green optical filters 16, 18 intended to affect the output of light *emitters* (e.g., LEDs), so as to produce the particular placement of windows within different openings associated with the light *detectors* (i.e., photodiodes) of any combination of Lumidigm, Scharf, and Kotanagi.

We are mindful that Lumidigm discloses that its sensor head 32 (Fig. 2) may be formed of optically opaque material. *See* Ex. 1006, 8:1–4. We, however, take note of Patent Owner's arguments that Petitioner's proposed opaque lateral surface structures illustrated in its composite figures from page 39 of the Petition (also reproduced *supra*) do not amount to such a surface that extends "through the protrusion" as required by each of claims 1, 19, and 26 or shows "opaque material lining a lateral surface of the windows" as required by claim 19. *See* Prelim Resp. 56–57. In our view, those arguments credibly point out shortcomings in Petitioner's approach to account for the structure and characteristics of the opaque surface requirements of the claims.

Additionally, although Lumidigm discloses a desire to "minimize[s] the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue" (Ex. 1006, 8:4–7), we see some merit in Patent Owner's argument that such disclosure does not amount to avoiding light piping or detecting unattenuated light as is required by some, if not all, of the claims (*see* Prelim. Resp. 57–58). As discussed above, in the context of the '501 patent, "light piping" is understood as light that bypasses a measurement site. *See, e.g.*, Ex. 1001, 22:48–50. As Patent Owner and Dr. Duckworth note, Lumidigm seemingly discusses light that is reflected after tissue attenuation and does not express that its sensor is structured to address situations in which entirely unattenuated light, i.e., light that has entirely

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bypassed the measurement site, is intended to not be detected. *See* Prelim. Resp. 57–58; Ex. 2002 ¶¶ 166–168.

After consideration of the record before us, we find questionable Petitioner’s and Dr. Kenny’s assessment and reasoning as to what a skilled artisan would have understood from the teachings of Lumidigm, Scharf, and Kotanagi as proposed by Petitioner here. We find persuasive Patent Owner’s arguments that Petitioner’s and Dr. Kenny’s assessments are grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art. *See, e.g.*, Prelim. Resp. 26–28. Dr. Duckworth’s testimony that one of ordinary skill in the art would not have combined the teachings of the prior art in the manner advocated by Petitioner further supports Patent Owner’s arguments. *See, e.g.*, Ex. 2002 ¶¶ 150–162, 171–178.

Based on the record here, we conclude that Petitioner has not shown a reasonable likelihood of success based on any of the proposed grounds that involve the combined teachings of Lumidigm, Scharf, and Kotanagi.<sup>10</sup>

### III. CONCLUSION

Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

### IV. ORDER

In consideration of the foregoing, it is

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<sup>10</sup> The additional teachings of Tran are not offered by Petitioner to overcome the deficiencies discussed with respect to the combination of Lumidigm, Scharf, and Kotanagi

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ORDERED that Petitioner's request for an *inter partes* review of claims 1–30 of the '501 patent is *denied* and no trial is instituted.

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Patent 10,912,501 B2

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# APPENDIX C

[Trials@uspto.gov](mailto:Trials@uspto.gov)  
571-272-7822

Paper 15  
Entered: January 24, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APPLE INC.,  
Petitioner,

v.

MASIMO CORPORATION,  
Patent Owner.

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IPR2022-01274  
Patent 10,912,502 B2

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Before JOSIAH C. COCKS, NEIL T. POWELL, and  
ROBERT A. POLLOCK *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

DECISION  
Denying Institution of *Inter Partes* Review  
35 U.S.C. § 314

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Patent 10,912,502 B2

## I. INTRODUCTION

Petitioner Apple Inc. filed a Petition (Paper 3, “Pet.”) requesting *inter partes* review of claims 1–30 (“the challenged claims”) of U.S. Patent No. 10,912,502 B1 (Ex. 1001, “the ’502 patent”).<sup>1</sup> Patent Owner Masimo Corporation filed a Preliminary Response (Paper 10, “Prelim. Resp.”). We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”).

Having considered the arguments and evidence presented in the Petition, for the reasons described below, we do not institute *inter partes* review.

### A. Related Matters

The parties state that the ’502 patent is the subject of *Masimo Corporation, et al. v. Apple Inc.*, ITC Inv No. 337-TA-1276. Pet. 1; Paper 5, 1. Patent Owner also identifies numerous additional patent applications, patents, and *inter partes* review proceedings as related to the ’502 patent. Paper 5, 1–3.

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<sup>1</sup> Petitioner additionally filed another Petition (IPR2022-01273) that also challenges claims 1–30 of the ’502 patent.

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*B. The '502 Patent*

The '502 patent is titled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User.” Ex. 1001, code (54). The '502 patent summarizes its disclosure as follows:

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

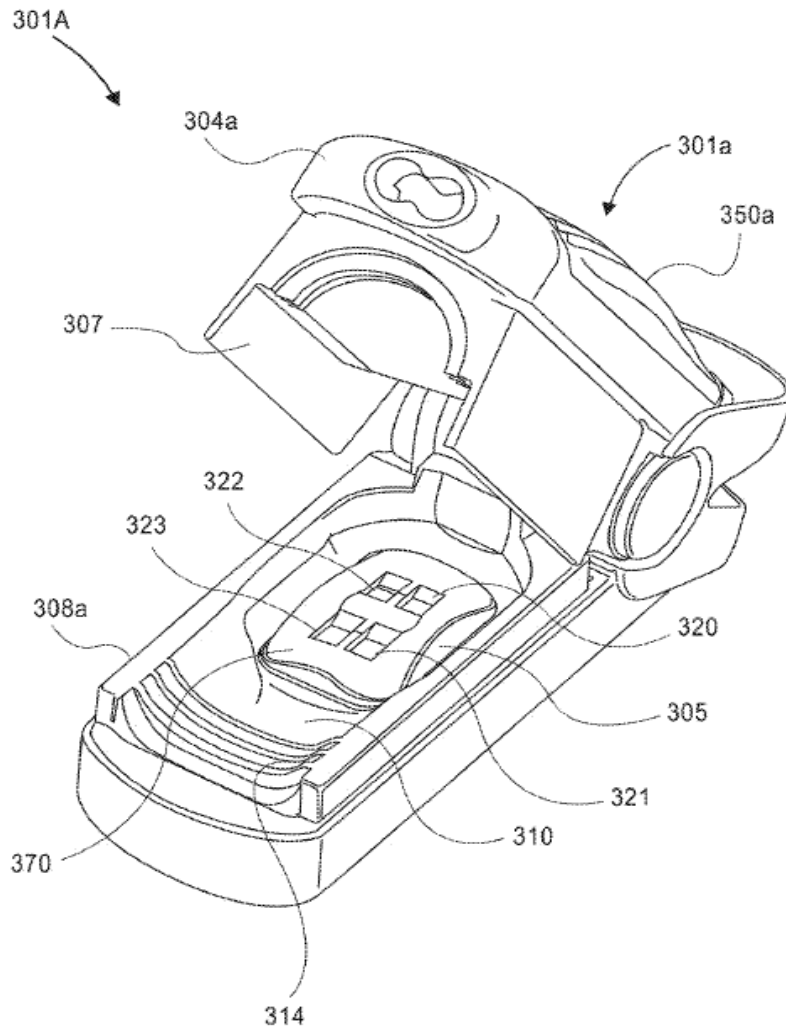
In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the noninvasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

*Id.* at 2:38–60.

The '502 patent describes that “[i]n noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.” *Id.* at 2:30–34.

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Figure 3C of the '502 patent is reproduced below:



**FIG. 3C**

Figure 3C above illustrates an example sensor including a finger bed protrusion according to an embodiment of the disclosure. *Id.* at 5:52–55. Sensor 301a includes detector shell 306a (not numbered in Figure 3c) with lower area 308a that can “include absorbing opaque material . . . to reduce ambient light entering the sensor 301a.” *Id.* at 19:4–12. Finger bed 310 includes convex protrusion 305 with openings or windows 320, 321, 322, and 322 that “mirror specific detector placement layouts such that light can impinge through the protrusion 305 onto” photodetectors (not illustrated in

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Figure 3C) that may be positioned beneath the protrusion. *Id.* at 19:42–48; 20:25–34.

### *C. Challenged Claims*

Petitioner challenges claims 1–30 of the '502 patent. Claims 1, 19, and 28 are independent claims. Claim 1 is representative and is reproduced below:

1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:

    a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

    a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

    four photodiodes arranged on an interior surface of the user-worn device and configured to receive light after attenuation by tissue of the user;

    a protrusion comprising:

        a convex surface extending over the interior surface, a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and

        a plurality of windows, each of the windows extending across a different one of the openings; and

    one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate a measurement of the physiological parameter of the user.

Ex. 1001, 44:63–45:23.

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*D. Alleged Grounds of Unpatentability*

Petitioner asserts the following grounds of unpatentability:

<b>Claims Challenged</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>
1–3, 5–7, 9, 11–18	103	Lumidigm, <sup>2</sup> Scharf, <sup>3</sup> Kotanagi <sup>4</sup>
4, 8, 10, 19–27, 28–30	103	Lumidigm, Scharf, Kotanagi, Tran <sup>5</sup>

Pet. 1. In addition to the references listed above, Petitioner relies on the Declaration of Dr. Thomas W. Kenny (Ex. 1003).

## II. ANALYSIS

### *A. Principles of Law*

A petition must show how the construed claims are unpatentable under the statutory grounds it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner bears the burden of demonstrating a reasonable likelihood that it would prevail with respect to at least one challenged claim for a petition to be granted. 35 U.S.C. § 314(a).

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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<sup>2</sup> U.S. Patent No. 7,620,212 B1 issued Nov. 17, 2009 (“Lumidigm,” Ex. 1006). Although Jeffrey G. Allen is listed as the first named inventor of the U.S. Patent No. 7,620,212 B2, Lumidigm, Inc. is listed as the Assignee. *See* Ex. 1006, code (73). Like the parties in their briefings in this proceeding, we refer to the noted patent as “Lumidigm.”

<sup>3</sup> U.S. Patent No. 6,330,468 B1 issued Dec. 11, 2001 (“Scharf,” Ex. 1025).

<sup>4</sup> PCT Application No. WO 2005/092182 A1 published Oct. 6, 2005 (“Kotanagi,” Ex. 1007 (English translation)).

<sup>5</sup> U.S. Patent No. 9,820,658 B2 issued Nov. 21, 2017 (“Tran,” Ex. 1008).

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*KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective indicia of non-obviousness (i.e., secondary considerations). *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

At this preliminary stage, we determine whether the information presented shows a reasonable likelihood that Petitioner would prevail in establishing that at least one of the challenged claims would have been obvious over the proposed prior art. We analyze the asserted grounds with the above-noted principles in mind.

### *B. Level of Ordinary Skill in the Art*

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom*



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*Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends the following in connection with a person of ordinary skill in the art:

A person of ordinary skill in the art relating to the subject matter of the '502 Patent as of July 3, 2008 ("POSITA") would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Pet. 2 (citing Ex. 1003 ¶¶ 40–41).

Patent Owner does not dispute this proposed level of skill. Prelim. Resp. 10.

For purposes of this Decision, we adopt Petitioner's proposal as reasonable and consistent with the prior art and the '502 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art may reflect an appropriate level of skill in the art).

### *C. Claim Construction*

We construe claims in the same manner used in a civil action under 35 U.S.C. § 282(b) "including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim

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language as it would have been understood by one of ordinary skill in the art in light of the specification. *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279–80 (Fed. Cir. 2017). Thus, we give claim terms their ordinary and customary meaning as understood by an ordinarily skilled artisan. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Neither party offers any express construction for any claim term. *See* Pet. 4; Prelim. Resp. 9. We determine that all claim terms should be given their ordinary and customary meaning and that it is unnecessary to make that meaning explicit for any term.

#### *D. Grounds Based on Lumidigm, Scharf, and Kotanagi*

Petitioner contends that all of the challenged claims (i.e., claims 1–30) are rendered obvious based, in part, on the combined teachings of Lumidigm, Scharf, and Kotanagi.<sup>6</sup> As expressed throughout its Preliminary Response, Patent Owner does not agree.

##### *1. Overview of Lumidigm*

Lumidigm is titled “Electro-Optical Sensor.” Ex. 1006, code (54). Lumidigm’s Abstract is reproduced below:

Methods and systems are provided that extend the functionality of electro-optical sensors. A device has a multiple light sources, a light detector, and a processor configured to

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<sup>6</sup> For claims 3, 4, 6, 9, 10, 20, 21, 23, 24, 26–30, Petitioner additionally relies on Tran.

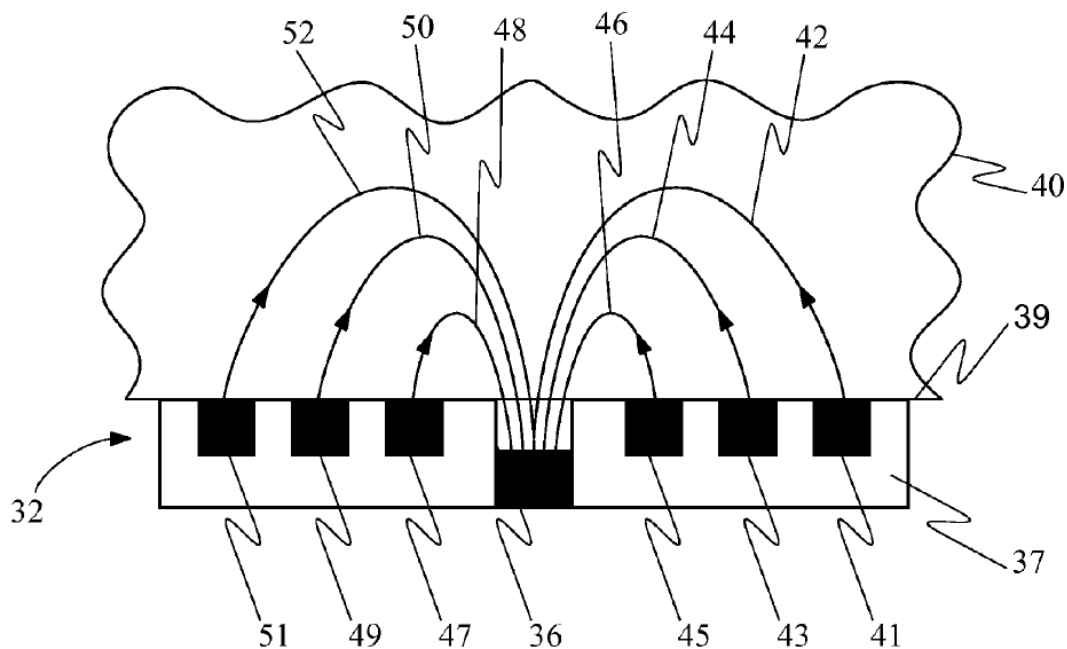
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operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector.

*Id.* at code (57).

Lumidigm's Figure 2 is reproduced below:

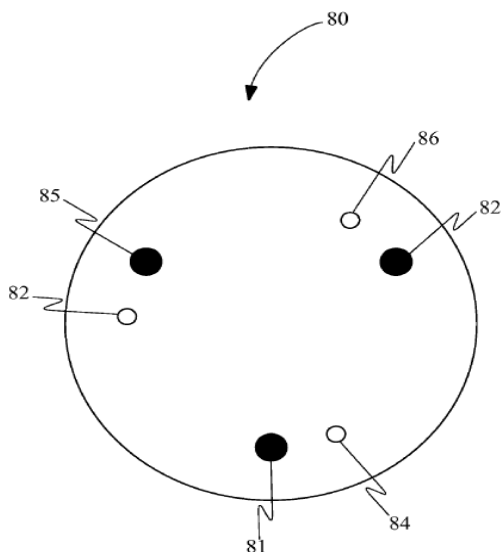


**FIG. 2**

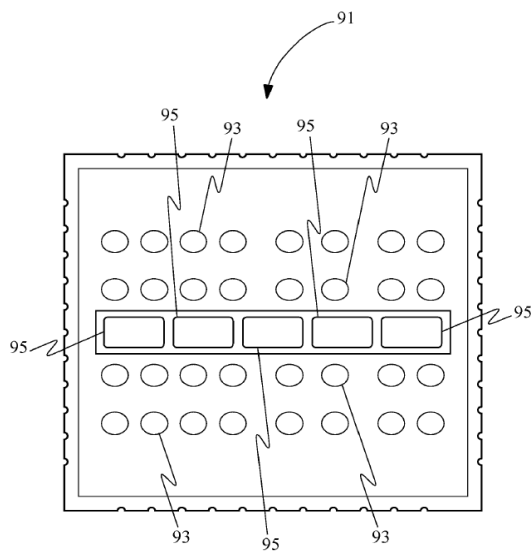
Figure 2 above depicts a “cross-sectional view of a biometric sensor element couple to a tissue surface showing multiple mean optical paths.” *Id.* at 4:45–47. Sensor head 32 includes light sources 41, 43, 45, 47, 49, 51 and detector 36. *Id.* at 7: 5–10. Optical paths 42, 44, 46, 48, 50, 52 show light passing through tissue 40. *Id.* Sensor head 32 is formed of optically opaque material 37.

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Lumidigm's Figures 6 and 7A are reproduced below:



**FIG. 6**



**FIG. 7A**

Figures 6 and 7A above illustrate top-views of biometric sensors according to two embodiments of the invention. *Id.* at 4:60–67. In Figure 6, light sensor 80 includes light sources 82, 84, 86 positioned relative to detectors 81, 83, 85. *Id.* at 9:14–16.<sup>7</sup> In Figure 7A, sensor 91 includes two rows of light sources 93 and one row of detectors 95. *Id.* at 9:27–30.

## 2. Overview of Scharf

Scharf is titled “System Using Green Light to Determine Parameters of a Cardiovascular System.” Ex. 1025, code (54). Scharf describes a reflectance oximeter that uses two green light sources to detect oxygen saturation of hemoglobin in a volume of intravascular blood. *Id.* at 2:39–42.

<sup>7</sup> It would appear that the reference character “82” on the right side of Figure 6 should read “83.”

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Scharf's Figure 3 is reproduced below:

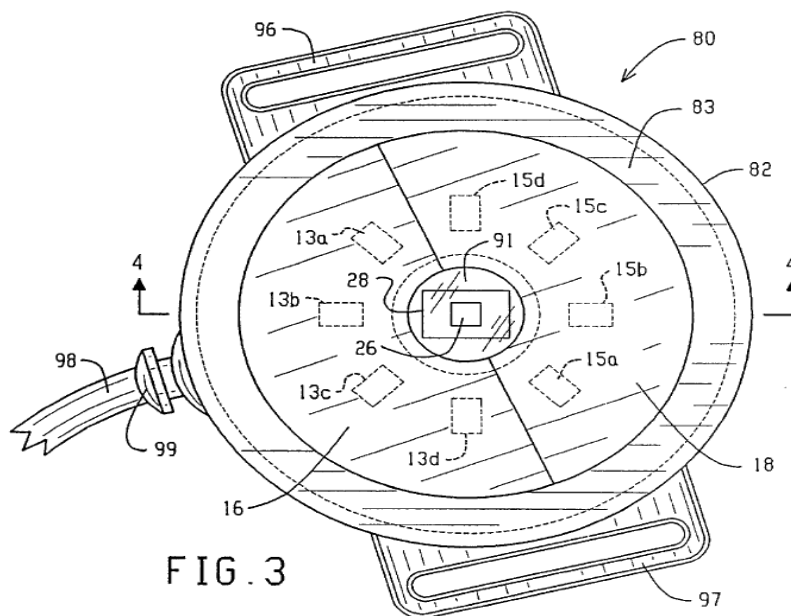


Figure 3 above shows a bottom plan view of an oximeter probe according to an embodiment. *Id.* at 3:40–41. The oximeter probe may include green lights formed of light emitting diodes (LEDs) 13, 15. *Id.* at 4:18–20. Scharf explains that, depending on the particular type of green light sources, green optical filters 16, 18 may be needed. *Id.* at 4:30–34.

### 3. Overview of Kotanagi

Kotanagi is titled “Biological Information Measuring Device.”

Ex. 1007, code (54). Kotanagi describes that a biological information measuring device can include a biological sensor including a body and a protrusion formed on the lower surface of the body. *Id.* at code (57).

Kotanagi explains that the protrusion can be formed with a “curved surface.” *Id.* ¶ 80.

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#### 4. *Discussion*

A principal feature of each of the independent claims of the '502 patent lies in the structure and arrangement of a “protrusion” located over four photodiodes arranged on an interior surface of a user-worn device. In particular, in claim 1 that feature reads as follows:

a protrusion comprising:  
     a convex surface extending over the interior surface,  
     a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and  
     a plurality of windows, each of the windows extending across a different one of the openings[.]

Ex. 1001, 45:11–19.

Thus, in claim 1, the protrusion feature requires a convex surface and multiple openings defined by an opaque surface and associated with a plurality of windows, with each window extending over a different opening. Independent claims 19 and 28 have similar requirements. Although not explicitly recited in claim 1, in the context of the '502 patent, the recited opaque surface is understood to aid in reducing “light piping” that reaches the photodiodes, which is an undesirable condition in which “light bypasses” the measurement site, e.g., human tissue, without being attenuated by that tissue. *See* Ex. 1001, 22:48–50; *see also* Prelim. Resp. 7–8 (description of light piping).<sup>8</sup>

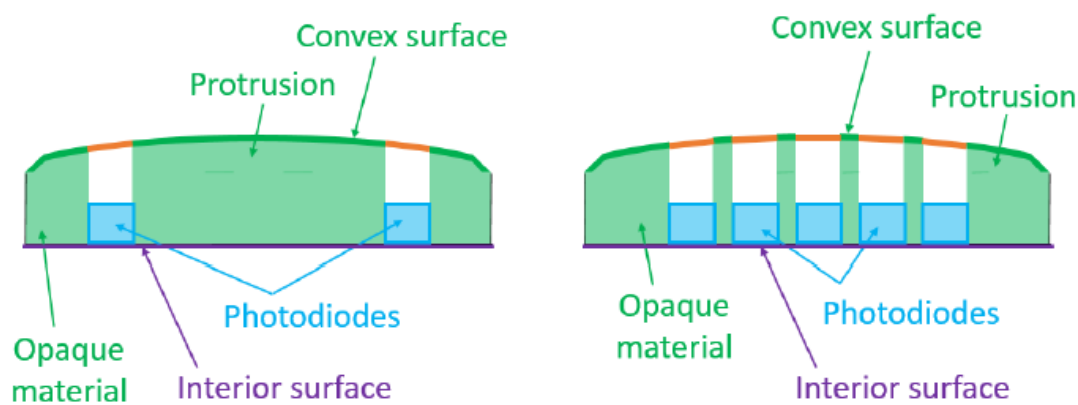
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<sup>8</sup> Independent claims 19 and 28, however, are explicit in reciting, respectively, that the opaque material is “configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue” (claim 19), and that that the “opaque surface [is] configured to reduce light piping” (claim 28).

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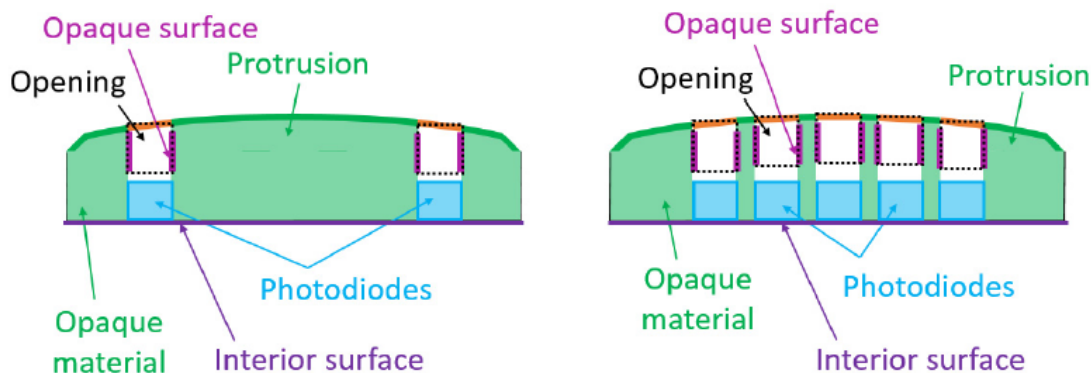
To arrive at the protrusion requirement in the claims, Petitioner presents composite or modified figures that Petitioner contends would have emerged from the teachings of Lumidigm and Kotanagi. Although Lumidigm does not present side views of the optical sensor that is illustrated in its Figures 6 and 7A (reproduced *supra*), Petitioner contends that based on the combined teachings of Lumidigm and Kotanagi, the following figures emerge:



Pet. 43–44 (citing Ex. 1003 ¶ 130). In Petitioner’s and Dr. Kenny’s view, and as depicted in the modified figure above, the application of Kotanagi’s curved surface to each of Lumidigm’s Figures 6 and 7A results in a “combination device” that “has a plurality of openings, one per photodiode, extending through the protrusion and positioned over the photodiodes.” *Id.* at 45 (citing Ex. 1003 ¶ 133) (emphasis omitted). The basis of Petitioner’s proposed ground of unpatentability, however, does not end there.

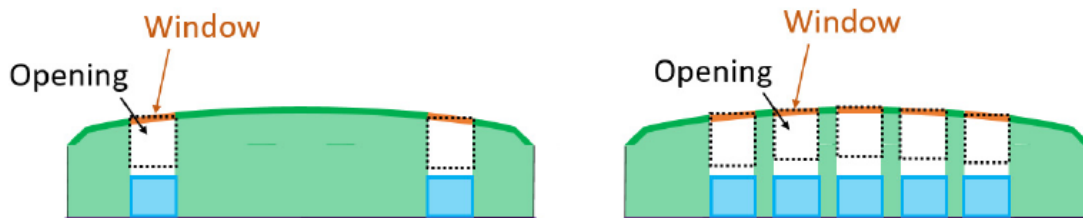
To account for the requirement, for instance, in claim 1 each opening is defined by an opaque surface, Petitioner offers the following additional “[c]omposite figures”:

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Pet. 45. According to Petitioner, the combined teachings of Lumidigm and Kotanagi additionally would be configured to include distinct opaque surfaces (shown in purple in the composite figures above) that extend along some portion of the recessed openings over each photodiode. *Id.*

Further still, in accounting for the requirements of the claims drawn to positioning different windows over each of the plurality of openings in the convex protrusion, Petitioner alleges that, in light of Scharf's teachings, the following further modified figures emerge:



*Id.* at 46.

Although it is certainly the case that an obviousness analysis may take into account the inferences and creative steps that a skilled artisan might glean from the teachings of the prior art (*see, e.g., KSR*, 550 U.S. at 418), one must be cognizant that “hindsight is not an available analytical mechanism to show obviousness.” *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1381 (Fed. Cir. 2007) (Newman, J., dissenting). Indeed, “we



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cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.” *See Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017).

Without the guidance provided by the claims of the ’502 patent, it is difficult to conclude that Petitioner’s postulation as to a particular structure that results from combining the teachings of Lumidigm, Kotanagi, and Scharf is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for Petitioner’s approach to arriving at the structural requirements of the claims.<sup>9</sup>

At the outset, we share Patent Owner’s view, and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings or windows for multiple detectors. *See, e.g.*, Prelim. Resp 28–29; Ex. 2002 ¶ 76. As discussed above, Petitioner attempts to arrive at such structure through a proposed amalgamation of prior art teachings that must include, for instance, arranging a convex protrusion with multiple openings or separate glass windows over Lumidigm’s optical sensors. In our view, however, Petitioner simply does not explain adequately why such configuration results from the actual teachings of the prior art.

Moreover, in an effort to next account for a convex shape of the protrusions and openings, Petitioner relies on Kotanagi’s curved protrusion

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<sup>9</sup> Although Petitioner, in a footnote, generally contends that “other examples” of composite figure configurations “could be conceived” so as to render the challenged claims obvious, Petitioner does not provide further assessment or explanation in that regard. *See* Pet. 13 n.5. We find that general contention inadequately supported.

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as providing, for instance, “better contact” and be “more comfortable” for a user of Lumidigm’s detector. *See, e.g.*, Pet. 28–29. Yet, consistent with the arguments advanced by Patent Owner and Dr. Duckworth, we are not satisfied that Petitioner adequately explains why a skilled artisan would have expected that such benefits would apply to the convoluted combination of modifications Petitioner proposes to arrive at the claimed invention. *See, e.g.*, Prelim. Resp. 41–50; Ex. 2002 ¶¶ 150–162. Nor has Petitioner explained adequately why a skilled artisan would have assessed that Petitioner’s reasoning applies to a protrusion configured to have specific characteristics, e.g., multiple distinct openings and opaque lateral surfaces, intended to provide a particular function, i.e., reduction of light piping, that is unaffiliated with concerns of contact or comfort. *See, e.g.*, Prelim. Resp. 41–51; Ex. 2002 ¶¶ 167–179.

Further still, we share Patent Owner’s skepticism (*see, e.g.*, Prelim. Resp. 69–72) that Petitioner’s reliance on Scharf’s teachings justifies Petitioner’s theory that different windows would be placed over different openings within a convex protrusion. *See, e.g.*, Pet. 31–32. Although Petitioner expresses that “glass covers” generally are known in the art, in our view, Petitioner does not explain adequately why the particular teachings of Scharf on which Petitioner relies give rise to the specific window configuration required by the noted claims. *See id.* Dr. Duckworth’s testimony supports Patent Owner’s argument that Scharf’s teachings applied to a combination of Lumidigm and Kotanagi do not convey reasonably to a skilled artisan the positioning of windows over the openings of a convex protrusion in the manner urged by Petitioner. *See, e.g.*, Ex. 2002 ¶¶ 189–195. Moreover, left wanting from Petitioner’s theories is why a person of ordinary skill in the art would seek to apply Scharf’s teachings as to a sensor

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face incorporating particular green optical filters 16, 18 intended to affect the output of light *emitters* (e.g., LEDs), so as to produce the particular placement of windows within different openings associated with the light *detectors* (i.e., photodiodes) of any combination of Lumidigm, Scharf, and Kotanagi.

We are mindful that Lumidigm discloses that its sensor head 32 (Fig. 2) may be formed of optically opaque material. *See* Ex. 1006, 8:1–4. We, however, take note of Patent Owner’s arguments that Petitioner’s proposed “opaque surface” structures illustrated in its composite figures from page 45 of the Petition (also reproduced *supra*) do not amount to such a surface that extends “through the protrusion” as required by each of claims 1, 19, and 28 or shows windows that are “lined with opaque material” as required by claim 19. *See* Prelim Resp. 56–57. In our view, those arguments credibly point out shortcomings in Petitioner’s approach to account for the structure and characteristics of the opaque surface requirements of the claims.

Additionally, although Lumidigm discloses a desire to “minimize[s] the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue” (Ex. 1006, 8:4–7), we see some merit in Patent Owner’s argument that such disclosure does not amount to avoiding light piping or detecting unattenuated light as is required by some, if not all, of the claims (*see* Prelim. Resp. 55–59). As discussed above, in the context of the ’502 patent, “light piping” is understood as light that bypasses a measurement site. *See, e.g.*, Ex. 1001, 22:48–50. As Patent Owner and Dr. Duckworth note, Lumidigm seemingly discusses light that is reflected after tissue attenuation and does not express that its sensor is structured to address situations in which entirely unattenuated light, i.e., light that has

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entirely bypassed the measurement site, is intended to not be detected. *See* Prelim. Resp. 55–59; Ex. 2002 ¶¶ 183–185.

After consideration of the record before us, we find questionable Petitioner’s and Dr. Kenny’s assessment and reasoning as to what a skilled artisan would have understood from the teachings of Lumidigm, Scharf, and Kotanagi as proposed by Petitioner here. We find persuasive Patent Owner’s arguments that Petitioner’s and Dr. Kenny’s assessments are grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art. *See, e.g.*, Prelim. Resp. 25–27. Dr. Duckworth’s testimony that one of ordinary skill in the art would not have combined the teachings of the prior art in the manner advocated by Petitioner further supports Patent Owner’s arguments. *See, e.g.*, Ex. 2002 ¶¶ 167–179, 183–185, 189–195.

Based on the record here, we conclude that Petitioner has not shown a reasonable likelihood of success based on any of the proposed grounds that involve the combined teachings of Lumidigm, Scharf, and Kotanagi.<sup>10</sup>

### III. CONCLUSION

Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

### IV. ORDER

In consideration of the foregoing, it is

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<sup>10</sup> The additional teachings of Tran are not offered by Petitioner to overcome the deficiencies discussed with respect to the combination of Lumidigm, Scharf, and Kotanagi.

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ORDERED that Petitioner's request for an *inter partes* review of claims 1–30 of the '502 patent Petition is *denied* and no trial is instituted.

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**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of  
CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**RESPONDENT APPLE INC.'S RESPONSE TO  
COMPLAINANTS' PETITION FOR REVIEW**

## II. THE POEZE PATENTS ('501, '502, '648 PATENTS)

### A. Issue No. 1: The ID Correctly Found '501 Claim 12 Obvious.

Complainants' petition provides no basis for reviewing the ID's correct conclusion that claim 12 of the '501 patent is obvious or the thorough factual findings on which that holding was based. The ID correctly found that Lumidigm "explicitly discloses" a user-worn device that is "configured to non-invasively measure physiological parameters of a user" and that satisfies all but one of the requirements of '501 claim 12, including "at least three LEDs, at least three photodiodes, a plurality of openings for each photodiode with opaque lateral surfaces, and a processor configured to calculate measurements of physiological parameters." ID 112. The ID further found that the last limitation—a "protrusion with a convex surface"—was obvious in view of Lumidigm combined with the knowledge of a POSITA, specifically that a POSITA "would have reason to modify the optical surface of the sensor head in Lumidigm's wristwatch based on Lumidigm's *explicit* suggestion of a sensor head with a 'compound curvature' for 'technical or stylistic reasons.'" *Id.*, citing RX-0411 at 7:57-63. The ID thus correctly concluded that the "combination of elements disclosed in Lumidigm and known in the prior art would have yielded a user-worn device meeting each limitation of claims 1 and 12, and one of ordinary skill in the art would have had a reasonable expectation of success in making such a combination." ID 112.

Complainants identify no legal errors in these findings. Moreover, their challenges to the ALJ's factual findings are not only inconsistent with the record but also raise new arguments never raised below and therefore waived. The Commission accordingly should decline review.

### 1. Substantial Evidence Supports The ID's Finding That Lumidigm Enabled Measuring Physiological Parameters.

Complainants' first argument—that Lumidigm does not enable physiological measurements—is new and therefore waived. Complainants never argued, anywhere in their pre-



hearing or post-hearing briefs, that Lumidigm does not **enable** the measurement of a physiological parameter, only that Lumidigm does not **disclose** one. *See* CPHB 86-97; CIB 124-129. Complainants’ new enablement argument accordingly is waived. *See Certain Subsea Telecommunications Systems & Components Thereof*, Inv. No. 337-TA-1098, Comm’n Op. at 38 (Oct. 21, 2019) (“Because Xtera did not raise this argument in its pre-hearing and post-hearing briefs, the Commission finds this argument waived.” (citing *Broadcom Corp. v. Int’l Trade Comm’n*, 542 F.3d 894, 901 (Fed. Cir. 2008) (party “waived that argument by failing to preserve it in the proceedings before the administrative law judge”)); Ground Rule No. 9.2.

Even if considered on its merits—which it should not be—Complainants’ argument fails. The ID correctly found that Lumidigm “describes functionality for measuring several different physiological parameters, e.g., hemoglobin levels, bilirubin, and blood alcohol.” ID 92. As the ID recognized, Lumidigm “clearly discloses additional ‘extended functionality’ using ‘the spectral-analysis capabilities of the biometric sensor,’ including where ‘the spectral analysis is used to identify a physiological state of an individual.’” ID 90 (quoting RX-0411 at 18:26-28). Lumidigm further discloses that this extended functionality can identify physiological states by “**measuring** the spectral variation of a **measured** spectrum for light scattered by the tissue, and comparing it with a reference spectral variation.” ID 90 (quoting RX-0411 at 18:29-32).

Complainants’ challenges to this finding as clearly erroneous are baseless. Indeed, given Lumidigm’s express disclosure of a wrist-worn device for measuring physiological parameters, there is a **presumption** of enablement. *See Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008) (“[A]n accused infringer ... enjoys a presumption that the anticipating disclosure also enables the claimed invention.”). Complainants identified **no** evidence supporting

their enablement argument before the ALJ, let alone “persuasive evidence” as would be necessary to overcome that presumption. *Id.*

To manufacture an issue for review, Complainants now—belatedly—attempt to argue an artificial distinction between a “spectrometer function” and a measurement function. CPFR 9. But as the Poeze patent specification itself confirms, a spectrometer function *is* a measurement function. The Poeze embodiments, like Lumidigm’s embodiments, use spectroscopy to measure “the properties of a material, e.g., glucose present in a measurement site” based on “the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light.” JX-001 at 33:53-59.

Complainants’ suggestion that Lumidigm’s spectrometer functions would not *measure* a physiological parameter is incorrect. CPFR 9. As the ID correctly recognized, Lumidigm explicitly states that its spectrometer functions do exactly that—they identify a “physiological state” by “*measuring* the spectral variation of a measured spectrum for light scattered by the tissue, and comparing it with a reference spectral variation.” ID 90 (quoting RX-0411 at 18:29-32 (internal quotation marks omitted)); *see also* RX-0411 at 4:10-16 (“A *measured* spectral variation is received in the form of electromagnetic radiation scattered from the tissue of the individual. The *measured* spectral variation is compared with a reference spectral variation over a predetermined wavelength interval by comparing, at each of a plurality of wavelengths . . . a property of the *measured* and referenced spectral variations.”). Lumidigm further explains that the “the physiological state of the individual is determined from a consistency of the *measured* spectral variation with the reference spectral variation” (4:17-19, 18:32-34) and provides multiple examples of such measurements including “concentration of a substance in the tissue of the

individual, such as a concentration of alcohol, bilirubin, or hemoglobin” (4:26-29), “oxygenation and/or hemoglobin levels in the blood” (19:24-28), “increases in alcohol levels” in the blood (19:44-48), and “levels of other toxins and/or drugs” in the blood (19:49-50).

Complainants focus on Lumidigm’s list of exemplary spectrometer functions and suggest that these functions would only detect color changes. As Dr. Warren confirmed, however, all examples on the list (including the unusual ones, like the fruit-ripeness function) are “known applications in reflectance spectroscopy.” Tr. [Warren] 1206:18-25. Although some of these functions compare colors of surfaces, Lumidigm is explicit that the *physiological* spectrometer functions measure *concentrations* in the tissue or blood. See, e.g., RX-0411 at 4:26-29 (“concentration of alcohol, bilirubin, or hemoglobin”), 19:24-28 (“oxygenation and/or hemoglobin levels in the blood”), 19:44-48 (“increases in alcohol levels” in the blood”), 19:49-50 (“levels of other toxins and/or drugs”). Complainants’ reliance on *Impax Labs. Inc. v. Lannett Holdings Inc.*, 893 F.3d 1372, 1379-80 (Fed. Cir. 2018), is therefore misplaced. In that case, unlike this one, there was no evidence that a POSITA would have understood how to implement the relevant compound in the claimed combination. To the contrary, the evidence indicated that the claimed compound would *not* have worked for that purpose.

Complainants suggest that the testimony of Lumidigm inventor, Robert Rowe, somehow supports their argument. CPFR 12. But the testimony Complainants cite is actually consistent with Lumidigm’s disclosures and confirms that Lumidigm’s hemoglobin function would measure a concentration of hemoglobin by receiving a “*measured* spectral variation” and comparing it to a reference spectral variation. RX-0411 at 4:10-16; see also *id.* at 18:29-32.

Complainants also attempt to draw parallels to the ID’s separate finding that Lumidigm does not enable taking an oxygen saturation measurement at the wrist to support their (new)

**3. The ID Made No Legal Error, And Substantial Evidence Supports Its Finding That Lumidigm's Openings Are Configured To Avoid Light Piping "Through The Protrusion."**

Complainants' contention that the ID "failed to address the claimed requirement of avoiding light piping '*through the protrusion*'" (CPFR 20) is also new. Complainants did *not* raise this issue in their post-hearing brief; their only argument for limitation [1E] was that Lumidigm does not disclose "*an opaque lateral surface or opaque material configured to avoid or reduce light piping,*" which the ID addressed and correctly rejected. *See* CIB 138-139; ID 106. Accordingly, this argument too is waived. *See supra* § II(A)(1).

And again, if considered—though it should not be—Complainants' new argument also fails on the merits because the ID correctly found that Lumidigm discloses limitation [1E]. Lumidigm expressly confirms that its detectors (36) are "recessed from the sensor surface 39 in optically opaque material" and that this optically opaque material "minimizes the amount of light that can be detected after reflecting off the first (epidermal) surface" and thus provides "optical blocking." RX-0411 at Fig. 2, 7:64-8:11. As Dr. Warren explained, the concept of using opaque materials for openings over photodiodes was another well-known idea, dating back to the "*late '60s*." Tr. [Warren] 1195:16-19. Lumidigm's reference to recesses made with opaque materials conveys the "quite well-known" idea that, "if you recess the photodiodes or detectors from the sensor surface in optically opaque material, you can reduce the amount of light that's detected without going through the tissue." *Id.* at 1211:10-1212:3. A POSITA would have understood that the use of opaque materials to form the openings through the protrusion over each detector "would have a role of helping to avoid light piping through the protrusion" (i.e., light traveling from the LEDs to the photodiodes without first passing through the user's tissue). Tr. [Warren] 1212:11-1213:3, 1228:16-23. Indeed, Lumidigm specifically discusses using openings made from opaque

materials to provide “optical blocking” for “shunted” light (another term for light piping). RX-0411 at 7:64-8:11; Tr. [Warren] 1212:22-1213; *see also* ID 107. The ALJ thus correctly found limitation [1E] met based on Lumidigm’s teachings and Dr. Warren’s testimony. ID 106-08.

Complainants’ contention that the ALJ ignored the latter part of the claim limitation in her findings is inconsistent with the ID. The ALJ found, in connection with limitations [1C] and [1D], that Lumidigm “explicitly discloses that its sensor head could have a ‘compound curvature on the optical surface’” (ID 103-04), that Lumidigm also teaches forming openings through that compound protrusion over the photodiodes (ID 105-06), and that it would have been obvious to form Lumidigm’s protrusion with a convex surface and with openings through the protrusion over the photodiodes (ID 105-06). Her finding that Lumidigm also teaches forming the openings from opaque materials to avoid light piping thus addresses the requirement of “opaque lateral surfaces configured to avoid light piping *through the protrusion*.”

Complainants’ suggestion that Lumidigm’s reference to light reflecting off the tissue “is a completely different phenomenon from light piping through the protrusion” (CPFR 21) ignores the record. As Dr. Warren explained, Mr. Kiani agreed, and the ID correctly found, it is light reflecting off the top surface of the tissue that has the potential to *cause* light piping because it can travel from the LEDs to the photodiodes *without* passing through the user’s tissue. *See* Tr. [Warren] 1212:2-1213:3 (confirming that “shunted” light referenced in Lumidigm “is what is called light piping in this matter”); Tr. [Kiani] 100:14-24 (describing “light piping” as “light that goes from the LED directly to the photodetector, without going *through* the tissue”); ID 107 (crediting Dr. Warren’s testimony that “Lumidigm’s descriptions of reflections that are ‘specular’ or ‘shunted’ light are consistent with the meaning of ‘light piping’ as that term is used in the context of the Poeze patents, because Lumidigm recognizes that this light bypasses the measurement site

head, made from opaque materials, “to implement the optical surface in a convex shape for the reasons that are explicitly disclosed in Lumidigm.” ID 101.<sup>4</sup>

**B. Issue No. 2: The ID Applied The Correct Law In Evaluating ’502 Claim 28 Element [28G], And Substantial Evidence Supported Its Finding.**

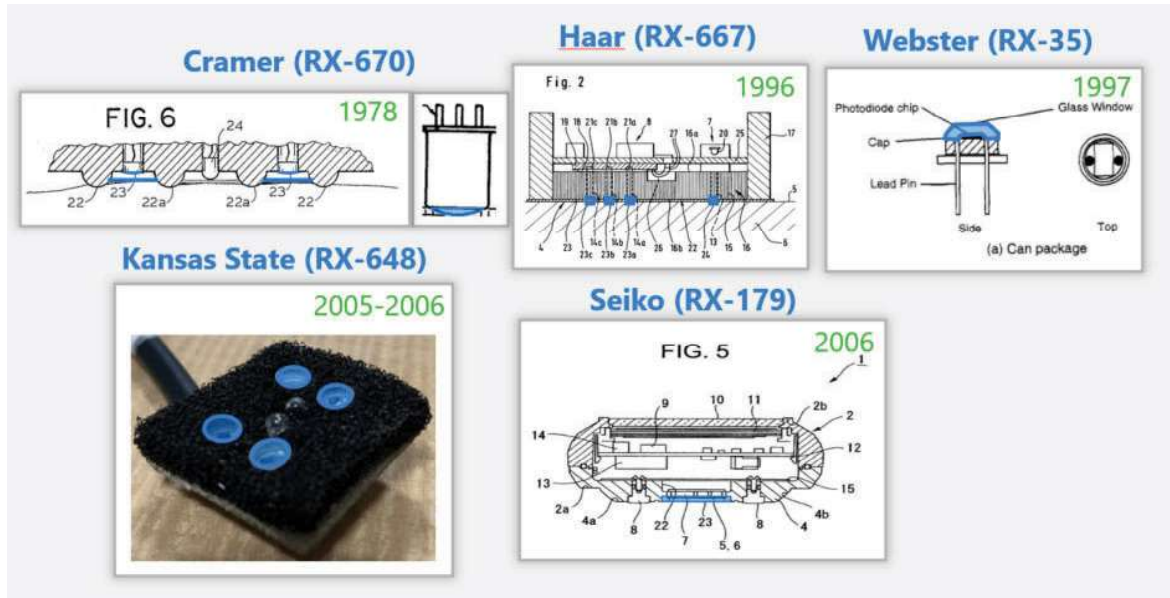
Complainants once again attempt to turn a factual issue into a legal one, claiming that the ID also applied the wrong legal standard in assessing the “transmissive windows” limitation. CPFR 23. Complainants have identified no such legal errors, however. Nor have they identified any clearly erroneous factual findings.

The ALJ correctly found that Lumidigm satisfies the “transmissive windows” limitation based on Lumidigm’s express teachings and Dr. Warren’s testimony on the state of the art. ID 131. As Professor Warren explained in the testimony cited in the ID, the use of transparent windows or other optically transparent materials, within or across openings over photodiodes, was “quite well-known” in the art, both to help transfer light and to protect the photodiodes from dirt

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<sup>4</sup> On January 24 and 30, 2022, the PTAB denied institution of Apple’s IPR petitions on the asserted Poeze patents. Those denials should not impact the issues here, because the petitions raised different grounds of invalidity. To be clear, had the PTAB granted those petitions based on different grounds and different prior art, that would have been yet further indication of the profound invalidity problems that previously led the PTAB to invalidate over 99% of over 300 challenged claims in other patents in the Poeze patent family. But the most recent denials lacked the benefit of the complete prior art record presented in the ITC. As the Commission and Federal Circuit have recognized in other contexts, while the Commission can take judicial notice of IPR proceedings—and Respondent has requested precisely that in its petition for review—the outcome of IPR proceedings are not binding upon the Commission, particularly where the Federal Circuit has not yet considered the issue. *Certain Hybrid Electric Vehicles and Components Thereof*, Inv. No. 337-1042, Notice of Investigation at 1 (Mar. 7, 2017) (Commission instituting investigation over proposed Respondents’ objection that asserted claims had been found unpatentable in IPR proceedings and were on appeal to Federal Circuit); *see also Nobel Biocare Servs. AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1375 (Fed. Cir. 2018), as amended (Sept. 20, 2018) (“We thus conclude that our prior affirmance of the ITC’s judgment on a different factual record ... does not dictate the outcome of this appeal [from an IPR decision].”); *Cisco Sys., Inc. v. Int’l Trade Comm’n*, No. 2017-2289 (Fed. Cir. Sept. 22, 2017) (declining to stay exclusion order pending inter partes review).

or debris. Tr. [Warren] 1193:24-1194:14, 1221:16-1222-9. Professor Warren provided many examples including those below:



*Id.*; see also RX-0035, RX-0179, RX-0670, RX-0648, RX-0667, RX0670. Consistent with this well-known idea, Lumidigm explains that its sensor can incorporate “an **optical relay** (not shown) between the sensor surface 39 and the skin 40” that “transfers the light . . . from the skin back to the detector(s) while minimizing light loss and spreading.” RX-0411 at 8:19-23. Lumidigm also identifies specific examples of such optical relays, including “**fiber optic face plates**,” “individual optical fibers,” and “fiber bundles,” and further confirms that “other mechanisms” are “known to one of skill in the art.” RX-0411 at 8:23-26.

As Dr. Warren further explained in the testimony cited in the ID, a POSITA would have understood that the fiber optic face plates, individual optical fibers, and fiber bundles referenced in Lumidigm were well known in the art, typically made of glass or plastic cladding, and could be placed within or arranged over the openings to transfer light and to protect the photodiodes. Tr.

[Warren] 1221:16-1222:25. A POSITA would have further understood that the fiber optics face plates referenced in Lumidigm could be implemented as a single faceplate or as individual faceplates over each opening and would have been motivated to implement either alternative. *Id.*

Complainants' contention that Apple provided no evidence that a POSITA would have been motivated to use separate windows over each opening (CPFR 23) is wrong. Dr. Warren confirmed that the use of transmissive windows extending across openings over photodiodes was "well-known" in the art and provided multiple examples. Tr. [Warren] 1221:16-1222:9, 1193:24-1194:14. He further confirmed that a POSITA would have understood that the "fiber optic face plates" *explicitly referenced* in Lumidigm could be implemented as a single face plate or as individual faceplates over each of the openings. *Id.* at 1221:16-1222:9. Contrary to Complainants' argument, this is not a case where the ALJ relied on "speculation" about what a POSITA could "theoretically" do. Instead, Lumidigm identifies and advocates the use of a *specific* structure—a "fiber optic face plate"—that a POSITA would recognize could be implemented in two ways. As the Supreme Court has held and the Federal Circuit has repeatedly confirmed, where a small number of alternatives are known in the art and a POSITA would understand how to implement them, they are obvious. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007) ("[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill."); *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1315 (Fed. Cir. 2008) (claim obvious where it recited one of "two alternative means" for communication, both of which "have long been known and understood by persons of ordinary skill in the art," and the prior art disclosed the other alternative means); *In re Law*, 303 F.2d 951, 953-54 (C.C.P.A. 1962) (confirming that choice between known "design alternatives" would be



obvious to a POSITA); *In re Kuhle*, 526 F.2d 553, 555 (C.C.P.A. 1975) (a “matter of design choice within the skill of the art” is obvious); *In re Magna Elecs., Inc.*, 611 F. App’x 969, 974 (Fed. Cir. 2015) (same); *see also Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020) (claims obvious based on disclosure of single prior art reference combined with knowledge of a POSITA); *Game & Tech. Co. v. Activision Blizzard Inc.*, 926 F.3d 1370, 1381 (Fed. Cir. 2019) (confirming that patent can be obvious based on single prior art reference if it would have been obvious to modify that reference to arrive at claimed invention).

Finally, the caselaw cited by Complainants does not support their arguments. *Adidas AG v. Nike, Inc.*, 963 F.3d 1355 (Fed. Cir. 2020), affirmed a finding that a combination was not obvious based on “[f]undamental differences [in methods] between” two prior art references. *Id.* at 1359. And *OSRAM Sylvania, Inc. v. American Induction Technologies, Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012), simply found a lack of evidence to support a summary judgment ruling. In this case, in contrast, there is no evidence of “fundamental differences” between two prior art references, and the full trial record provided substantial evidence supporting the finding.

**C. Issue No. 3: The ID Applied The Correct Law In Analyzing The Protrusion Comprising A Convex Surface Elements Of The ’502 And ’648 Claims, And Substantial Evidence Supports Its Findings.**

For the reasons discussed above (*supra* § III(A)(3)), the ID correctly found Lumidigm rendered Limitation [1C] of the ’501 patent obvious. Complainants have not identified any legal errors in the ID’s analysis. Nor have they identified any clearly erroneous factual findings. Complainants’ similar arguments regarding the ’502 and ’648 claims should be rejected.

Further, the claimed invention was the entirety of the “slide-to-unlock” invention. *Id.* Here, to the contrary, the asserted claims do not cover all pulse oximetry.

Indeed, it is Complainants—not the ALJ—that seek to impose an improper legal standard by suggesting that it was Apple’s burden to demonstrate a lack of nexus between the success of the Accused Apple Watches and Complainants’ claimed invention. *See* CPFR (arguing “Apple never explained why” the alleged commercial success is “is not largely attributable to the pulse oximetry feature”). It was not. *See MRC Innovations, Inc. v. Hunter Mfg., LLP*, 747 F.3d 1326, 1336 (Fed. Cir. 2014) (“As the patentee, it was [the patentee]’s burden of production to demonstrate a nexus between the claimed design and the secondary considerations.”). *See also Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1034 (Fed. Cir. 2016) (“If the commercial success is due to an unclaimed feature of the device or if the feature that creates the commercial success was known in the prior art, the success is not pertinent.”) (internal quotation marks omitted); *id.* (“[T]he Covidien products contained numerous unclaimed features, “such as ergonomic design, precise articulation, and reloads that provide simpler selection and reduced inventory,” which may instead have been responsible for the commercial success of the products.”).

Complainants’ contention of “clear error” in the ALJ’s factual findings with respect to commercial success is similarly baseless. The record established that Complainants did not show evidence of commercial success attributable to the claimed invention sufficient to affect the obviousness analysis—let alone overcome the *prima facie* obviousness case. Complainants admit that “the data shows that Apple was unable to increase its market share” (CPFR 28) with the introduction of the Blood Oxygen feature into its Watches. Complainants never connected the success of the Accused Apple Watches—which contain a myriad of features as the ID properly

recognized (ID 155)—to the Blood Oxygen feature, let alone to the accused functionality within the Blood Oxygen feature. To the contrary, the ID correctly observed that “[t]he evidence shows that much of the success of the Apple Watch Series 6 can be attributed to the growing market for smartwatches rather than the specific implementation of the pulse oximetry feature claimed in the patents-at-issue.” ID 155.

Unable to reasonably dispute this, Complainants pivot to contending that the “price premium” between the Series 6 and the SE is evidence of commercial success—a point they have never made in this litigation. *See* CPHB 134-35; CIB at 173-75; CIB 94-96. Because it was not raised before the ALJ, this argument is waived. *See Subsea Telecommunications Systems*, Comm’n Op. at 38; *Broadcom*, 542 F.3d at 901; Ground Rule No. 9.2.

Even if considered (which it should not be), this new argument fails on the merits. Nothing other than Complainants’ say-so connects the sales and price differential between Apple Watch models to the accused feature. According to Complainants, commercial success is evident from the fact that consumers overall purchased [REDACTED]

[REDACTED] Complainants contend that this alleged willingness to pay more is directly tied to the Blood Oxygen feature. But even this statistic is misstated. Complainants cherry-picked data from a single quarter of Apple Watch sales and exaggerate the alleged premium. CPFR 26-27. The starting price difference between Series 6 and the SE was \$399 compared to \$279 (33%)

[REDACTED] CX-0252 at 20. Moreover, numerous differences exist between the SE and Series 6 Watch. Complainants’ own brief acknowledges two others that were advertised: the ECG app and Always-On Retina display. CPFR 28. Complainants have failed to provide any reliable data showing what actually drives the difference in sales between the Series 6 and SE. *Compare Apple Inc.*, 839 F.3d at 1055-56 (jury considered customer surveys indicating

“that customers would be less likely to purchase a portable device without the slide to unlock feature and would pay less for products without it”). The only evidence specific to consumers’ use of the Blood Oxygen feature was that it is “[REDACTED]h” (CX-0275C [Caldbeck Dep.] at 65:21-22, 66:3-12), which Complainants wrongly reject as “not relevant” without any explanation.

**2. The ID’s Findings Of No Evidence of Skepticism Or Unexpected Results Regarding Convex Surfaces Were Correct.**

The ID is correct that there was no skepticism of “convex surfaces” or that the use of such surfaces led to unexpected results. Complainants’ assertion that the ID made both legal and factual errors in analyzing specific testimony and evidence related to skepticism or unexpected results regarding the convex surfaces is unsupported.

Complainants claim the ID committed “legal error” by “ignoring” Madisetti’s testimony and his explanation of Mendelson ’799, stating that the “ID did not provide any analysis of this testimony and did not even mention it.” CPFR 30. This is wrong. The ID expressly and substantively addressed Complainants’ contentions regarding Mendelson ’799 (CX-1733) and Dr. Madisetti’s testimony regarding it (ID 145-146, citing and discussing CX-1733 and Tr. [Madisetti] at 1374:9-12) but rejected it. As discussed above, in § II(A)(2), the ID correctly recognized that Mendelson does not even discuss a convex surface—a finding that Complainants do not dispute. ID 102. Moreover, contrary to Dr. Madisetti’s testimony, many other references in the field, including Lumidigm, Seiko 131, Nippon, and Cramer, all taught the use and benefits of convex or other protrusions, and these benefits were well known. Tr. [Warren] 1244:11-1246:12. The ID

testimony— namely, that there was no written description support for two sets of LEDs each with LEDs emitting at the same “first wavelength” and “second wavelength.” Tr. [Warren] at 1247:13-17. Instead, Complainants’ **only** contention in their pre-hearing brief (and initial post-hearing brief) was that “the specification discloses embodiments with multiple, spaced apart emitters having sets of LEDs to emit light at two or more wavelengths.” CPHB 126, *citing* CX-0001 at Figs. 7A-7B, 13, 14I; 9:60-63, 12:9-12, 12:13-25, 13:16-21, 33:30-38, 21:51-54, 38:8-22. CIB 179-80 (same statement). The ID correctly rejected this contention because the claims require **more** than two sets of LED emitting “at two or more wavelengths.” Specifically, they require “**matching** wavelengths in **each** set of LEDs.” ID 163.

## **2. The Poeze Specification Supports The Finding Of Lack Of Written Description.**

Complainants accuse the ALJ of engaging in an examination of the specification “untethered from any expert testimony.” CPFR 34. To the contrary, the ID walked through the portions of the specification that Complainants had identified in their post-hearing briefs and confirmed, consistent with Dr. Warren’s testimony, that **none** discloses two sets of LEDs each with LEDs emitting at the same “first wavelength” and “second wavelength.” ID 163-64 (“Consistent with Dr. Warren’s testimony these disclosures would not convey to persons of ordinary skill in the art that sets of LEDs with matching wavelengths were part of the alleged invention—there is no suggesting that two LEDs emit the same wavelengths or any benefit ascribed to such a pairing[.]”).

Complainants attempt to rebut these findings by offering a lengthy, entirely new analysis of the Poeze specification. Complainants made **none** of these arguments in their pre- or post-hearing briefs, however, and they accordingly are waived. *See* CPHB 123-27; CIB 175-80; Ground Rules 9.2, 13.1; *In re Baxter Int’l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012).

And again, even if the Commission were to consider these new arguments—which it should not—they are also wrong. Complainants focus on the Poeze specification’s discussion of “emitter 104.” CPFR 36-40. The specification confirms, however, that emitter 104 can be essentially *any* kind of light source emitting at *any* wavelength—it can be a single light source, an array, or a set of LEDs (JX-001 at 12:12-17, 13:16-20) and can emit at “any of a variety of wavelengths of visible or near-infrared radiation” (13:5-8), from as little as 905 nm to as much as 1800 nm (12:37-39, 12:64-13:8, 13:22-25). In short, the specification states that these emitters can be anything, and never at *any* point provides a written description of the very specific emitters referenced in the claims—two sets of LEDs each with LEDs emitting at the same “first wavelength” and “second wavelength.”

Complainants’ suggestion that a single reference to “*sets* of optical sources that are capable of emitting visible *and* near-infrared [light]” could somehow support their argument (CPFR 37) is inconsistent not only with the specification, but also with basic laws of physics. As the Poeze specification itself confirms, “visible and near-infrared light” are *not* specific wavelengths. Instead, each encompasses a large spectrum of *different* wavelengths. See JX.001 at 13:5-8 (confirming that emitter 104 “can transmit any of a variety of wavelengths of visible or near infrared optical radiation”).

Complainants also point to various references in the specification to sets of LEDs emitting at two or more wavelengths of light. CPFR 37. Consistent with the ALJ’s findings, however, *none* of these references describes two sets of LEDs each with LEDs emitting at the *same* “first wavelength” and “second wavelength”—as the claims require, with “*matching* wavelengths in *each* set of LEDs.” ID 163.

Examiner found Cheung lacks a thermal mass, and is therefore precluded by the prosecution history. *Id.*

**4. Complainants Failed To Prove Infringement Under The Proper Construction Of “Bulk Temperature For The Thermal Mass.”**

The Accused Apple Watches contain a thermistor that measures a local temperature at one point on the module where the thermistor sits. RPHB 219-22; RRB 123-27. For example, Dr. Mehra testified that the thermistor [REDACTED]

[REDACTED] Tr. [Mehra] 888:20-24; *id.* at 892:5-10 (thermistor measures temperature at “[REDACTED]

[REDACTED] Dr. Mehra also explained that the thermistor cannot [REDACTED]

[REDACTED] Tr. [Mehra] 890:18-23. Even Mr. Goldberg admitted that the [REDACTED]

[REDACTED] which is “a specific location at a specific point in time.” Tr. [Goldberg] 645:19-646:3; *id.* at 647:17-20 (thermistors “measure the temperature in the region in which they’re located”); ID 268-71.

Complainants presented no evidence that the thermistor measures a representative temperature for the thermal mass. RPHB 222-24; RRB 123-27. Notably, Mr. Goldberg did not offer an opinion on what was the representative temperature of the board at any point in time, and therefore he could not opine on whether the thermistor measured that temperature. *Cf.* Tr. [Mehra] 892:11-893:6 (Complainants’ counsel arguing that Dr. Mehra “has no foundation” to testify whether the thermistor measures “the average temperature of the board” because “he would need to establish that he has knowledge of the average temperature of the board and that he has made

such measurements”). Thus, the ID found that Complainants failed to show that the temperature measured by the thermistor is a “bulk temperature for the thermal mass.” ID 271.

Complainants establish no clear error or legal error in the ID. Complainants cursorily assert that they have already shown “the Accused Products have [REDACTED] [REDACTED] and that somehow “also establishes that the [REDACTED] is a representative temperature for the thermal mass.” CPFR 66. Complainants never presented this argument before, and it is waived. Moreover, it is wrong on both counts. Complainants never showed that the Accused Apple Watches have a thermal mass that stabilizes a bulk temperature. Instead, Complainants expended ten pages ignoring that requirement and tried to show Apple measures a temperature that “correlates with, and, thus, can be used to determine, LED operating wavelengths.” CPFR 56; *supra* § V(A)(2). And even if Complainants had shown a mass stabilizes a bulk temperature (they did not), that could not *automatically* show that the thermistor measures a representative temperature for the thermal mass.<sup>21</sup> Such an automatic assumption would render the latter limitation meaningless, which is improper as a matter of claim construction. Nor is the assumption logically valid, because a thermistor can only measure a local temperature at one portion of the board, and it need not necessarily be placed at a point where the temperature is representative for the thermal mass. *See supra* § V(A)(3). Complainants failed to show that the local temperature measured by a properly positioned thermistor coincides with the representative temperature for the thermal mass. *See* RPHB 222-23; RRB 122.

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<sup>21</sup> Complainants cite the ID’s findings regarding the “bulk temperature” limitation in the Early Rainbow Sensors. CPFR 66. The ID erroneously found that the Early Rainbow Sensors meet the “bulk temperature” limitation for purposes of the domestic industry technical prong, and its findings should be reversed on that issue. RPFR 82-84. But, in any event, those findings are irrelevant to what is practiced by the Accused Apple Watches because they pertain to different products, and Complainants have not shown any bulk temperature stabilization in the Accused Apple Watches much less a thermistor measurement of the bulk temperature.



**Via Electronic Submission**

Ronald A Traud, Esq  
Office of the General Counsel  
U.S. International Trade Commission  
500 E Street S.W.  
Washington DC, 20436

**Re: Inv. No. 337-TA-1276**

Dear Mr. Traud

- My name is Chris McCarthy. I am submitting this response to the Commission's solicitation of comments on public interest issues raised by the ALJ's recommendations for relief in Investigation No. 337-TA-1276. The recommended relief is in the public interest given the need to protect the patent rights of medical device innovators from the threat of companies such as Apple who can afford to infringe as a mere cost of doing business.
- I am a New Jersey licensed respiratory therapist and the director of cardiopulmonary services at an acute care hospital. I value the relationship and services innovative companies, such as Masimo, provide to my patients and me. Their innovations make a difference in the care provided to patients, particularly Masimo in the acute care setting.
- In my experience, Masimo has become synonymous with innovation in patient monitoring and patient safety. New innovations have continued to emerge from Masimo since its inception, when it revolutionized pulse oximetry technology. Since then, Masimo has continued to innovate with non-invasive measurements that no other company in the world offers, such as non-invasive total hemoglobin, carboxyhemoglobin and methemoglobin measurements. Prior to Masimo, the only way to measure these physiological parameters was through a blood draw. Despite them having been on the market for many years from Masimo, no other company has presented any competitive technology. We are concerned that if Masimo's intellectual property were not respected and enforced, that would necessarily drive reduced innovation from such an innovative company. Masimo's early revolutionary technology was initially copied by the largest supplier of pulse oximetry, and Masimo prevailed at trial and appeal, succeeding in protecting its intellectual property. Even as Masimo has grown, it has continued to invest much of the returns on sales of its revolutionary technology into new innovations, such as those described above. That is the purpose of protecting innovative advances. This is particularly important in healthcare, where many patient markets are small, yet require very substantial investments.

- Patient care and consumer health are both dependent on the availability of equipment designed specifically to meet clinical accuracy. The Masimo W1 is a truly innovative device. Masimo is now making its cutting-edge medical-grade non-invasive physiological monitoring that has significantly contributed to the medical care available to the public.
- Masimo's technology has led to a significant reduction in errors for calculating the blood oxygen levels in neonates, saving countless individuals from a lifetime of eye-damage. In fact, the success of Masimo's SET Technology has been shown in clinical studies showing a strong positive association between the use of pulse oximetry with SET and a reduction in the incidence of ROP.<sup>1</sup>

Sincerely,

Christopher McCarthy

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<sup>1</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1651-2227.2010.02001.x>



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**#1or 2 respiratory hospital in the U.S.**  
*US News & World Report*

U.S. International Trade Commission  
500 E Street, S.W.  
Washington, D.C. 20436

Re: Support for the Apple Watch for use in tracking physiologic features in medical patients.

Dear Members of the U.S. International Trade Commission:

I am writing to support Apple and their wearable device (Apple Watch). For the past 10 years I have conducted medical research studies involving wearable sensors that measure physiologic parameters (heart rate, physical activity, oxygen saturation, and temperature) in medical patients. We have published results in peer-reviewed medical journals (e.g., Bowler R, et al. *BMJ Open Res* 2019;6:e000350. doi:10.1136/bmjresp-2018-000350) and presented our findings at scientific meetings (e.g., the American Thoracic Society). We have used both medical research devices (Actigraph) and consumer devices (Apple Watch, FitBit). A key feature of consumer devices is their integration of multiple sensors and particularly oxygen saturation (SpO2) for patients with respiratory diseases. In these patients from our research studies and personally my research group has found the Apple Watch to be an exceptional device that accurately measures important parameters such as heart rate, physical activity, and oxygen saturation. Coupled with monitoring apps, these parameters help predict the onset of acute illness. The devices are also significantly less expensive than research only devices and depriving consumers of the devices might unnecessarily limit access to remote medical monitoring in underserved groups (e.g., rural patients) who do not have ready access to specialists. I am happy to provide additional information to the Commission upon request. I do not have any conflict of interest other than many of these companies have provided these devices at substantial discount for research studies.

Sincerely,

A handwritten signature in black ink, appearing to read "Russell Bowler".

Russell Bowler, M.D., Ph.D.,  
Director of COPD Clinic and Precision Medicine  
Professor of Medicine  
Division of Pulmonary Medicine, Department of Medicine  
National Jewish Health, Denver, Colorado  
1400 Jackson Street, Room K715a  
Denver, Colorado 80206  
Phone: 303 398 1639  
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**STEPHEN J. RUOSS, M.D.**

Professor of Medicine

Clinical Chief

Division of Pulmonary, Allergy and Critical Care Medicine

February 21, 2023

U.S. International Trade Commission  
500 E Street, S.W.  
Washington, D.C. 20436

Re: Apple Watch with blood oxygen saturation monitoring feature

Members of the U.S. International Trade Commission,

I am writing to you as an academic pulmonary specialist physician as well as an elite athlete, in reference to the action before you regarding the Apple Watch with blood oxygen saturation monitoring feature. I am writing this letter to express my strong support for the blood oxygen saturation monitoring feature of the Apple Watch. I am not supported by Apple, Inc., and have no conflicts of interest regarding this subject or this letter to the Commission.

The oxygen saturation feature of the Apple Watch is a highly accurate device feature, with performance characteristics fully comparable to medical device standards for oximeters.

The oximetry feature of the Apple Watch is an important and very useful component of the physiology assessment capabilities of the Watch, which also include electrocardiogram (ECG) and irregular rhythm notification (IRN) features. These coupled assessment tools allow the Watch user to have a very sophisticated and useful composite view of their physiology, providing the benefit of highly accurate, important, and immediate information for their use.

One of the primary benefits of the blood oxygen monitoring feature is its ability to alert users to potential health issues. This feature can help users identify changes in their blood oxygen levels that may indicate a respiratory or cardiac problem, allowing them to seek medical attention promptly. Additionally, this feature may be particularly valuable for individuals who engage in high-altitude activities or suffer from sleep apnea, as it can help them monitor their oxygen levels and adjust their behavior accordingly.

Furthermore, I believe that the Apple Watch has a strong reputation for safety and effectiveness. Apple is a company that has demonstrated a commitment to user privacy and data security, which is especially important when it comes to health-related data. As a result, I have confidence that the blood oxygen monitoring feature on the Apple Watch is safe, accurate, and reliable.

In conclusion, as a pulmonary physician as well as an elite endurance athlete, I feel that the blood oxygen saturation monitoring feature of the Apple Watch is a highly valuable feature for Apple Watch users, and I strongly support retaining it as a component of the physiology monitoring capabilities of the Watch.

Sincerely,

A handwritten signature in blue ink, appearing to read "Stephen Ruoss".

Stephen Ruoss, MD

February 22, 2023

**VIA EDIS**

The Honorable Lisa R. Barton  
Secretary  
U.S. International Trade Commission  
500 E Street, S.W.  
Washington, D.C. 20436

Re: ***Certain Light-Based Physiological Measurement Devices and Components Thereof,***  
**Inv. No. 337-TA-1276**

To the International Trade Commission,

My name is Dr. David Albert. I am the founder and Chief Medical Officer of AliveCor. Over the years, I have published more than 100 peer-reviewed medical abstracts and articles principally in the Cardiology literature and have served on the faculty of the American College of Cardiology, American Heart Association, Heart Rhythm Society, Heart Failure Society of America and the Computing in Cardiology meetings. My focus is the development of innovative noninvasive Cardiovascular technology and I am an acknowledged expert in electrocardiographic technology.

I make this submission on behalf of Masimo, which I understand is seeking to exclude Apple Watches that infringe its patents. Although I cannot comment on Masimo's patents themselves (because I have not studied them in detail), I can say from personal experience that Masimo is well-known as an innovator in the world of medical devices, particularly innovations for wearable devices. Not only have I recommended Masimo products but I own a Masimo MightySat pulse oximeter device and would only rely on that to monitor my family when we had COVID. I have no commercial interest in Masimo and have never received any payment from the company; I just think their products are the best pulse oximeters in the world.

In this investigation, my understanding is that Apple argues the public interest will be harmed if Masimo is successful in excluding infringing Apple Watches. I strongly disagree. Failing to exclude infringing devices will harm the public interest, not the other way around.

First, Apple's insinuation that Apple Watches are the only devices in the country that can provide pulse oximetry capabilities is wrong. Apple Watches provide consumer-grade pulse oximetry capabilities, and I know from personal experience there are many similar consumer-grade pulse oximeters in every pharmacy and online. In contrast, Masimo provides a clinical-grade pulse oximeter to consumers, which is far more reliable than consumer-grade offerings. Excluding Apple Watches will therefore not reduce the number of clinical-grade pulse oximeters in the U.S., and there will remain numerous consumer-grade pulse oximeters nationwide. The idea that individuals will suddenly have no option for heart health if infringing Apple Watches are excluded from the market thus does not fit with the facts.

Second, intellectual property rights are hugely important to the advancement of public health. I am an inventor and know firsthand the sorts of incentives that go into the decision to spend the amount of time, thought, and (often) money necessary to develop a new medical technology. My own company, AliveCor, recently suffered similar infringement from Apple and successfully vindicated its intellectual property rights before this Commission, which was hugely vindicating for the effort we put into developing our own heart health products and to protecting the investment we put into those products. While it is certainly true that improving medical access and overall human health is its own reward, the practicality of the invention process is that the ability to monetize or otherwise protect a new medical invention is necessary. Without that protection, innovators have less reason to innovate, and less certainty that their hard work will pay off. And, without as many innovators trying to push forward medical technology, society suffers as a result. For a company like Masimo—that has already contributed so much to the next phase of heart health—failing to protect its innovations will have hugely negative effects on other innovators in the medical community.

Apple did not come up with the pulse oximetry technology it now touts as one of the major reasons to purchase an Apple Watch. I believe the public interest will be best served by sending Apple and powerful companies like it a message that they must respect intellectual property rights and not try to stamp out competition from the true innovators simply to make another dollar. By protecting Masimo (just like it did AliveCor), the Commission will better serve the public interest than allowing Apple to make a few billion extra dollars through stolen technology.

Sincerely,

A handwritten signature in dark ink, appearing to read "David Albert", with a long horizontal flourish extending to the right.

David E. Albert, M.D.

Founder and Chief Medical Officer

AliveCor, Inc.





The Max Harry  
**Weil Institute**  
FOR CRITICAL CARE RESEARCH & INNOVATION

North Campus Research Complex  
2800 Plymouth Road  
Ann Arbor, MI, 48109  
(734) 647-4751

Via Electronic Submission

The Honorable Katherine M. Hiner  
Acting Secretary  
U.S. International Trade Commission  
500 E Street, S.W.  
Washington, D.C. 20436

Re: *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv.  
No. 337-TA-1276

To the International Trade Commission,

My name is Kevin Ward, MD and I am a Professor in the Departments of Emergency Medicine and Biomedical Engineering at the University of Michigan. I am also a Fellow of both the American College of Emergency Physicians and the American Academy of Emergency Medicine. Prior to joining the University of Michigan in 2012, I was Professor and Associate Chair of Emergency Medicine at Virginia Commonwealth University (VCU) where I also founded and directed the VCU Reanimation Engineering Science Center (VCURES). I write in response to the Commission's solicitations of comments regarding the public interest, and in support of the suggested remedial orders against Apple. For the reasons described below, in my opinion, the Apple Watches with pulse oximetry capabilities does not benefit public welfare, and certainly not in any manner that outweighs the public's interest in strong intellectual property rights.

My research interests span the field of critical illness and injury ranging from combat casualty care to the intensive care unit. I develop and leverage broad platform technologies capable of use throughout all echelons of care of the critically ill and injured as well as in all age groups including noninvasive monitors and predictive algorithms. My work has been funded by the NIH, Department of Defense, NSF, and industry. My passion is in creating programs which encourage true integration across the disciplines of medicine, engineering, data sciences, and entrepreneurship that accelerate discovery to true patient impact. I am the founder of and executive director of the Max Harry Weil Institute for Critical Care Research and Innovation which is the largest critical care research enterprise in the U.S. I also led the design and implementation of Michigan Medicine's Fast Forward Medical Innovation program and served as its inaugural Executive Director from 2013-2018. I am a serial innovator and entrepreneur in the field of emergency and critical care medicine and the recipient of Innovation and Commercialization awards from Virginia Commonwealth University, the University of Michigan Medical School, and the Department of Defense. I am a named inventor on numerous patents and have founded over 8 companies. Five of my inventions have resulted in FDA approved products.

In collaboration with the U.S. Army and its Joint Special Operations Training Medical Center, I developed and medically directed special training programs, which have been responsible for providing clinical training to over 1000 Special Operation Combat Medics. For this work, the

*Transforming critical care through innovation, integration, and entrepreneurship.*

**Appx24204**



Department of the Army and the Joint Special Operations Training Center awarded me a Certificate for Patriotic Civilian Service. I am also a Lieutenant Colonel in the U.S. Army Medical Corps and its 948th Forward Resuscitation Surgical Team deploying to Afghanistan in support of Operation Freedom's Sentinel and the 10th Special Forces Group (Airborne).

I have published over 200 peer-reviewed articles and book chapters. I am the recipient of the Society of Academic Emergency Medicine's Excellence in Research Award as well as the American College of Emergency Physicians Outstanding Contributions in Research Award. I serve on numerous editorial and review boards in the field of resuscitation, emergency and critical care medicine, and also serve on the executive committee for the Trauma Hemostasis and Oxygenation Research (THOR).

Transformative lifesaving technologies do not get to a patient's bedside by themselves. The process requires a deep understanding of physiology, intellectual property, regulatory challenges, the market, as well as numerous other areas. This work costs significant amounts of resources, including time and money. The way innovators are able to protect such investments and hopefully recoup the investment is through intellectual property rights. Without enforcing such rights, the investments in companies developing life altering technologies will lose all incentive, and the public health will be the victim. For that reason alone, I support the exclusion rights as being in the public interest.

I am also very concerned about the proliferation of "medical devices" like the Apple Watch with pulse oximetry. These are not "medical devices" as the FDA would use the term. Indeed, I understand only software associated with the ECG feature of certain Apple Watches is FDA cleared. Apple has not received FDA clearance for its pulse oximeter and based on data collected by Masimo, it is certainly not clear Apple would receive FDA clearance for its pulse oximeter.<sup>1</sup> Despite this, it is my belief that confusion abounds in that many patients and medical professionals believe or at least use devices such as the Apple Watch as if they are FDA approved.

Specifically, Masimo's White Paper comparing the Masimo W1 to the Series 7 Watch with pulse oximeter obtained an adjusted  $A_{RMS}$  that would not meet current FDA clearance requirements. The results show the Series 7's pulse oximeter should not be used by medical professionals or patients, particularly because continuous measurements of blood oxygen saturation in patients is typically required.

I have serious concerns regarding patients treating an Apple Watch pulse oximeter as a medical device when such use has not been cleared by the FDA. Patients typically rely on large household brand-name technical companies like Apple to provide products that are beneficial, and not simply contain novelty functionalities. Apple's advertising of these medical functionalities appears to be an attempt to mislead the public into purchasing the devices as if it were a medical

<sup>1</sup> [https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A\\_Whitepaper\\_Masimo\\_W1\\_US\\_v4.pdf?v=1670952306](https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A_Whitepaper_Masimo_W1_US_v4.pdf?v=1670952306) ("White Paper")





aid. I was shocked to see a video for the Apple Watch with pulse oximetry (referred to blood oxygen saturation) as something important to patients in view of the COVID-19 pandemic.<sup>2</sup> Although using blood oxygen saturation is useful for a physician, that does not mean the Apple Watch is capable of providing meaningful data—in my view it is not the type of device patients or physicians should rely upon for any medical purpose.

Moreover, contrary to the representations made by Apple in its marketing, the Apple Watch is not something that patients worried about COVID-19 should be relying on especially when there are FDA approved alternatives available. The Apple watch does not provide continuous measurements, much less claim to have medical grade capabilities in the pulse oximetry feature. Thus, I believe Apple's insinuation in the video that its watch is capable of providing "an indication of how well [your cardiovascular system] is functioning and of your overall respiratory and cardiac health" endangers public health. These current parameters provided and advertised by Apple simply do not have the fidelity and accuracy required for medical decision making.

In summary, I believe Apple's pulse oximetry, combined with its sale and marketing of that feature, has potential to harm the public health. Apple should not be allowed to use the inventions of other innovators based on unsupported allegations that its products might help people achieve improved outcomes. The public's interest in strong intellectual property rights, which will dictate future investments in future live-saving technologies, far outweighs the public's need for these novelty devices.

Very Respectfully,

Kevin R. Ward, MD, FACEP, FAAEM  
 Executive Director: Max Harry Weil Institute for Critical Care Research and Innovation  
 Professor Departments of Emergency Medicine and Biomedical Engineering  
 University of Michigan Medicine  
 LTC U.S. Army MC

57156261

<sup>2</sup> <https://www.youtube.com/watch?v=YKQFaPRObp8> at 2:42-3:28.

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**PUBLIC INTEREST STATEMENT OF NON-PARTY PETER PRONOVOST, MD**

My name is Peter J. Pronovost, M.D., Ph.D., F.C.C.M, and I am the Chief Quality & Clinical Transformation Office at University Hospitals. I am a patient safety champion, innovator, critical care physician, a researcher (publishing over 800 peer reviewed publication), entrepreneur (founding a health care start-up that was later acquired) and a global thought leader on health policy. My scientific work leveraging checklists to reduce catheter-related bloodstream infections has been shown to have saved thousands of lives. Time Magazine has named me one of the 100 most influential people in the world and in 2008. I received the MacArthur Foundation's Fellowship often referred to as a "genius grant." I chronicled my work helping improve patient safety in my book, *Safe Patients, Smart Hospitals: How One Doctor's Checklist Can Help Us Change Health Care from the Inside Out*.

Founded in 1886, University Hospitals serves the needs of patients through an integrated network of 21 hospitals (including five joint ventures), more than 50 health centers and outpatient facilities, and over 200 physician offices in 16 counties throughout northern Ohio. As Chief Quality & Clinical Transformation Officer, I am charged with fostering ideation and implementation for new protocols to eliminate defects in value and thereby enhance quality of care; developing new frameworks for population health management for UH's more than one million patients; and managing the UH Accountable Care Organization (ACO) Network – one of the nation's largest – comprising more than 581,000 members. In this role, I champion a new focus of keeping people "Healthy at Home." I am also a professor of anesthesiology and critical care medicine, surgery, nursing, and health policy and management at the Johns Hopkins University School of Medicine.

Previously, I served as the Senior Vice President for Patient Safety and Quality at Johns Hopkins Medicine as well as the founder and director of the Johns Hopkins Medicine Armstrong

Institute for Patient Safety and Quality. In this role, I worked to eliminate all harms in one health system following on success in eliminating one harm in most health systems across the U.S. I also served as the Senior Vice President for Clinical Strategy and the Chief Medical officer for UnitedHealthcare. I was elected to the National Academy of Medicine in 2011, elected as Fellow of the American Academy of Nursing and has received multiple honorary degrees. I am an advisor to the World Health Organizations' World Alliance for Patient Safety and regularly address U.S. Congress on patient safety. In response to a White House executive order, I co-chaired the Healthcare Quality Summit to modernize the Department of Health and Human Services quality measurement system.

I write to in response to the Commission's solicitation of comments on public interest issues raised by the ALJ's recommendations for relief in Investigation No. 337-TA-1276. In my view, the recommended relief serves the public interest given the strong public interest in incentivizing investment into medical innovations, which protect life-changing and life-saving technologies. Since the Pandemic, patients are using home monitoring devices as diagnostic tests and assume that devices on the market are accurate to make those diagnoses. Yet the accuracy of these home devices varies widely especially among non-medical grade devices. The continued use by patients of non-medical-grade devices such as the Apple Watch pulse oximetry puts those patients at risk for misdiagnosis and harm. The patients assume that these devices provide accurate diagnosis, and unfortunately that assumption is largely inaccurate with non-medical grade devices. Misdiagnosis is one of the major causes of preventable harm and FDA can reduce this harm by ensuring that devices used for home diagnoses are medical grade. The public interest statements from those claiming to rely on those measurements for their medical care did not provide studies supporting such use, and I am not aware of such studies.

The Apple Watch takes measurements on demand, but the user's hand must be in a particular position and remain motionless. The devices can also take intermittent measurements, provided that same motionless specific position is met. The Apple Watch does not provide continuous measurements. The lack of effectiveness of the Apple Watch is illustrated by Masimo's White Paper, which compares the Masimo W1 to the Apple Watch Series 7 oximeter.<sup>1</sup>

Table 7 of the White Paper illustrates how the Apple Watch is insufficient for patients, catching less than 7% of the dangerous desaturation events, compared to the Masimo W1 catching 100% of such events. By detecting such a low percentages of desaturations, the Apple Watch is simply not reliable enough to be useful.

**Table 7.** Tabulated Summary of Fast Desaturation Events and Detection Rates for Masimo W1 vs Apple Watch

Test Configuration	Number of Subjects	Number of Valid Events	Detection Rate for Masimo W1	Detection Rate for Apple Watch
Configuration 1	7	49	49/49=100%	3/49=6.1%
Configuration 2	8	60	60/60=100%	4/60=6.7%

Detection Rate = (Nt / Ndesat) x 100 (%), Nt = Number of Detected Event by Test Device, Ndesat = Number of All Valid Fast Desaturation Events by Reference SpO<sub>2</sub>

Masimo's White Paper also casts serious doubts on the measurements obtained by the Apple Watch Series 7. Although the Masimo W1 tracks measurements taken via blood draws closely, the Apple Watch—even when it gets a reading—is not at clinical-grade accuracy.

<sup>1</sup> [https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A\\_Whitepaper\\_Masimo\\_W1\\_US\\_v4.pdf?v=1670952306](https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A_Whitepaper_Masimo_W1_US_v4.pdf?v=1670952306) ("White Paper")

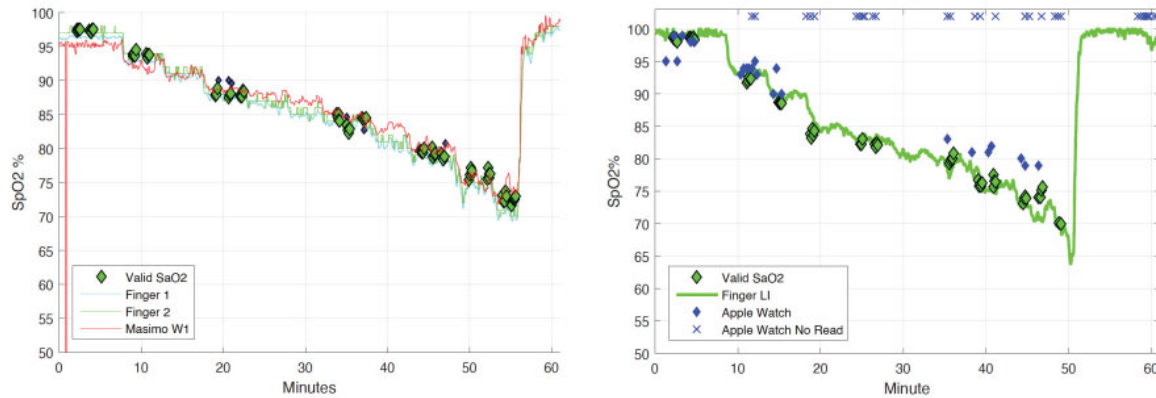


Figure 5.

**Representative saturation vs time plots from subjects monitored with Masimo W1 (left panel) and Apple Watch (right panel) during blood desaturation studies.** Masimo W1 SpO<sub>2</sub> values are recorded as red line. The Apple Watch SpO<sub>2</sub> values are shown as blue diamonds when values could be obtained. When no value could register, an "X" is shown at the top. The valid reference arterial blood saturation (SaO<sub>2</sub>) value is shown in green diamonds for each device. There are two additional SpO<sub>2</sub> references (from Masimo RD SET<sup>®</sup> Sensors) shown for the Masimo W1 study (Fingers 1 and 2) and one additional SpO<sub>2</sub> reference for the Apple Watch (Finger LI). The Masimo W1 tracked with the reference pulse oximeters and SaO<sub>2</sub> values quite well. However, there are numerous examples of "failure to read" (X) for the Apple Watch.

The calculated A<sub>RMS</sub> for the Apple Watch indicates that the device could not be cleared by the FDA and is unlikely to actually assist patients

Table 6. Tabulated Summary of Performance Statistics for Masimo W1 and Apple Watch

	Bias (%)	Precision (%)	A <sub>RMS</sub> (%)	Adjusted Precision (%)	Adjusted A <sub>RMS</sub> (%)
Masimo W1	0.2	1.5	1.5	1.6	1.6
Apple Watch	3.1	3.2	4.4	3.4	4.6

Despite physicians touting the devices ability to calculate blood oxygen saturation, Apple states in its marketing material "Blood oxygen app measurements are not intended for medical use, including self-diagnosis or consultation with a doctor, and are only designed for general fitness and wellness purposes."<sup>2</sup> I have concerns that patients will not understand this distinction and, as reflected in other public interest statements, are relying on the Apple watch to diagnose hypoxemia and monitor trends and response to treatments. No doubt, consumers love Apple

<sup>2</sup> <https://support.apple.com/en-us/HT211027>

products; but this increases the risk that consumers will use the watch for medical purposes. This could result in false negatives, underdiagnosed hypoxemia and false positives where people may unnecessarily seek healthcare and cause psychological distress. Indeed, the Journal of the American Medical Informatics Association published a study concluding false positives from the Apple Watch “may lead to overutilization of healthcare resources.”<sup>3</sup>

Additionally, as someone who started a small-company, I understand the importance of strong intellectual property rights to innovation. Masimo is an innovation leader, and its products have been proven to have clinical benefit. It serves the public interest to provide incentives for the innovators to bring the next life-saving devices to market. Accordingly, the enforcement of Masimo’s intellectual property rights will help foster future investment and innovations in healthcare. This will have a real impact on patient healthcare.

In sum, the Apple watch pulse oximeter is not medical grade, yet people claim to be using it as a medical device, potentially causing harm. I support the recommended remedial orders and believe they are in the public interest. I encourage the Commission to block the importation of Apple Watches that include the pulse oximetry sensor. To the extent other consumers desire the other features, Apple has the watches like the Apple Watch SE readily available. I also encourage the FDA to require that pulse oximeters be medical grade as we have no way to ensure consumers will not use them for medical purpose, and when they do, it can cause them harm.

Respectfully submitted,

Dated: February 26, 2023

/s/ Peter Pronovost

Peter Pronovost, MD

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<sup>3</sup> <https://academic.oup.com/jamia/article/27/9/1359/5911974?login=false>

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**PUBLIC INTEREST STATEMENT OF NON-PARTY  
MEDICAL DEVICE MANUFACTURERS ASSOCIATION (MDMA)**



Non-party the Medical Device Manufacturers Association (MDMA) responds to the Commission's solicitation of comments on public interest issues in Investigation No. 337-TA-1276. The recommended relief is in the public interest given the need to protect the patent rights of medical device innovators from the threat of large companies who can afford to engage in "efficient infringement" as a business strategy.

### **The Medical Device Manufacturers Association Supports Enforcement of IP Rights**

MDMA is a national trade association in Washington, DC providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies. MDMA's mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical technology. Since 1992, MDMA has been the voice for medical innovation, proactively helping to shape policies that impact the innovators. To achieve its goals, MDMA represents its members' collective interests before the United States Congress, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and other federal agencies that develop or implement policies that affect the medical device industry. MDMA is particularly concerned about continued erosion of intellectual property rights of its members, who must protect their innovations to ensure that medical technology flourishes.

### **Apple's Lack of Respect for Innovation**

Over several years, Apple has executed a strategy to position its consumer products not only within the health and wellness space, but also within the healthcare field. This includes an emphasis on healthcare applications of Apple products.<sup>1</sup> In its push to extend the reach of its consumer products, Apple has disregarded the patent rights of innovators. Apple founder Steve Jobs welcomed the practice of taking others' ideas. In Jobs' view, "[i]t's better to be a pirate than join the navy," and he embraced Picasso's adage, "good artists copy, great artists steal."<sup>2</sup> Jobs emphasized that Apple has "always been shameless about stealing great ideas."<sup>3</sup>

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<sup>1</sup> <https://www.apple.com/healthcare/> (claiming "Our technology helps [healthcare providers] work effectively within hospitals, connect remotely with patients, and conduct groundbreaking medical research").

<sup>2</sup> <https://qz.com/1719898/steve-jobs-speech-that-made-silicon-valley-obsessed-with-pirates/>.

<sup>3</sup> <https://thenextweb.com/news/steve-jobs-shameless-stealing-great-ideas>.

**Apple's Practice of "Sherlocking" Innovations from Third Parties**

In 2011, Apple created a section in its AppStore referred to as "Apps for Healthcare Professionals," which it later divided into subcategories such as reference, medical education, EMR and patient monitoring, nursing, imaging, patient education, and personal care.<sup>4</sup> In 2014, Apple released its own "HealthApp" and a developer platform called HealthKit to allow developers to make health apps that integrate with Apple's app.<sup>5</sup> Unfortunately, Apple has developed a reputation for mining internal data from these apps to exploit the ideas of its developers.<sup>6</sup> The experience of having an app or feature become obsolete because Apple has copied it is referred to as "Getting Sherlocked."

**Apple's Targets Include Medical Device Innovators**

One target of Apple's piracy are medical device innovators such as Masimo, the Complainant in this Investigation which has grown from a startup to the leading supplier of hospital pulse oximetry in the world. Masimo alleges that Apple approached it years ago, seeking to incorporate Masimo's technology into Apple products. But instead, Apple opted to recruit Masimo engineers and executives, and eventually released the infringing products. Masimo is also bringing its medical grade technologies directly to consumers. Masimo has released directly to consumers a pulse oximeter worn on the user's wrist that *continuously* measures a user's oxygen saturation, known as the Masimo W1. A recent article comparing the Masimo W1 to the Apple Watch explains that the "Masimo W1 feels like a tool" contrasting that to the Apple watch as more like a "toy."<sup>7</sup> It explains that the W1 is better for continuous monitoring for health reasons. *Id.*

Masimo previously introduced wrist-worn, continuous, wireless, hospital pulse oximetry technology for home use during COVID-19, with Masimo SafetyNet. This product provided hospital grade

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<sup>4</sup> See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4029126/>

<sup>5</sup> <https://www.cnn.com/2016/05/24/tim-cook-why-the-apple-watch-is-key-in-the-enormous-health-care-market.html>

<sup>6</sup> Reed Albergotti, "How Apple uses its App Store to copy the best ideas," *The Washington Post*, September 5, 2019, available at <https://www.washingtonpost.com/technology/2019/09/05/how-apple-uses-its-app-store-copy-best-ideas/>

<sup>7</sup> <https://www.verywellhealth.com/health-tracking-watches-masimo-vs-apple-7111935>

pulse oximeters for the home. The data is transmitted to the hospitals, allowing them to monitor patients from their homes. This was the only such product, and it received substantial news coverage for its innovative approach to solving the hospital overcrowding issue.<sup>8</sup>

Apple's expressing interest in a company's medical device technology, only to then enter the market using such technology without permission, was also the subject of another Investigation of Apple -- in 337-TA-1266, which also resulted in a finding of a Section 337 Violation by Apple. The infringement was by the Apple Watch that has been found to infringe Masimo's patents, but the infringing medical technology is different. The use of Masimo's technology heightens this theft, because unlike AliveCor, Masimo is the leading pulse oximetry supplier to hospitals worldwide. Its technology has proven to offer clinical benefits above other pulse oximeters<sup>9</sup> and to improve clinical outcomes.<sup>10</sup>

Apple's conduct as alleged by Masimo, AliveCor and others indicates a pattern of "efficient infringement"—which has been described as "the use of another company's patents without authorization on the understanding that litigation will be too slow to meaningfully stop the infringement and will ultimately only result in the payment of a royalty if the suit is lost." <sup>11</sup>

Apple's former patent counsel stated that such a practice could be viewed as a "fiduciary responsibility" for "cash-rich firms that can afford to litigate without end."<sup>12</sup> Apple has claimed to repudiate these comments, but its conduct suggests an Efficient Infringement strategy to quickly get new products and features on the market to curb competition.

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<sup>8</sup><https://www.youtube.com/watch?v=pDozdvvbCMA>; [https://www.youtube.com/watch?v=2SskwKPn\\_u4](https://www.youtube.com/watch?v=2SskwKPn_u4); <https://www.youtube.com/watch?v=I7ul1vGWcQM>; <https://www.youtube.com/watch?v=Iv10FJy32vs>

<sup>9</sup> <https://www.masimo.com/evidence/pulse-oximetry/set/>

<sup>10</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1651-2227.2010.02001.x>; de-Wahl Granelli A et al. *BMJ*. 2009;Jan 8;338., and Zhao et al. *Lancet*. 2014 Aug 30;384(9945):747-54; McGrath S, et al *J Patient Safety*. 2021; 17(8):557-561;

<sup>11</sup> <https://docs.house.gov/meetings/JU/JU05/20200729/110883/HHRG-116-JU05-20200729-QFR059.pdf>

<sup>12</sup> *Id.*; see also <https://cpip.gmu.edu/2016/10/12/supreme-court-should-not-reward-efficient-infringement-in-apple-v-samsung/>; <https://ipwatchdog.com/2019/03/19/apple-pays-patent-infringement-important-legal-cases-continue/id=107425/>

This strategy ignores that “the public interest favors the protection of intellectual property.” *Certain Digital Television Products and Certain Products Containing Same and Methods of Using Same*, Inv. No. 337-TA-617, Comm’n Op., at 9 (Aug. 21, 2009) (“Digital TV Products”) (internal quotation marks and citation omitted). The ITC should deny relief only where “the statutory public interest concerns are so great as to trump the public interest in enforcement of intellectual property rights.” *Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543, Comm’n Op., at 153-154 (June 19, 2007). The Commission “need only decide that the public interest does not preclude” the remedy. *Certain Cigarettes and Packaging Thereof*, Inv. No. 337-TA-643, 2009 ITC LEXIS 2464, Comm’n Op., at \*46 (Oct. 1, 2009).

Any argument by Apple that the remedial orders should be avoided due to widespread use of its infringing Apple Watch should be rejected. That would be tantamount to arguing if you can infringe in a huge way, then you should escape the consequences. Such a policy encourages infringement. Enforcement should also not depend on the size of the company subject to the remedial orders. Apple’s assertion that it has many customers for its infringing Watches does not justify Apple’s infringement or provide an excuse.

MDMA believes that protecting intellectual property rights is particularly important in medical technology, where innovation has saved countless lives and improved the quality of life for countless others. The investment required to bring innovative technologies to market is enormous, involving not only a commitment to product development but also to clinical research, which is necessary to validate the safety and efficacy of medical technology. Masimo has made these investments and healthcare has improved as a result. Allowing the theft of technology from pioneering companies seriously undermines the ability of companies to raise the funds necessary to innovate and continue to improve healthcare for Americans.

#### **There are Alternative Options to the Infringing Pulse Oximetry Feature**

Apple has heavily marketed pulse oximetry on the Apple Watch, but numerous other wrist-worn devices that also provide non-medical pulse oximetry are available on the market from companies such as

Fitbit, Samsung, Garmin, Amazon and others.<sup>13</sup> In addition, Masimo offers the W1, which offers clinical grade continuous pulse oximetry. We understand that this same Masimo W1 is sold to hospitals outside the United States. Philips, the world leader in multi- parameter, critical care patient monitors, recently announced it will add compatibility to the Masimo W1 for telehealth.<sup>14</sup> The Apple Watch, on the other hand, provides sporadic measurements, only under perfect conditions.

**Apple Can Remove the Infringing Features Without Consumer Impact**

Apple also already sells the Apple Watch SE, which offers the smartwatch features of the Apple Watch at issue in this Investigation, without the infringing pulse oximetry. And Apple releases a new version of the Apple Watch every year and certainly has resources to remove infringing features while including other features not at issue.

**The Recommended Remedies Support American Innovation**

MDMA believes providing companies with appropriate relief at the ITC is essential to protect American innovation and encourage innovative companies to pursue real medical solutions. An exclusion order and cease-and- desist order preventing Apple from importing and distributing products that rely on Masimo's innovation are the appropriate remedies. A conclusion otherwise would encourage "efficient infringement" by Apple and others and would disincentivize innovation. This will have a dramatic impact on smaller companies who do not have the resources to compete unless they can protect their innovations.

Sincerely,



Dated: February 27, 2023

Mark Leahey  
President & CEO  
Medical Device Manufacturers Association (MDMA)

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<sup>13</sup> <https://www.androidcentral.com/best-smartwatches-can-measure-blood-oxygen-saturation-levels>

<sup>14</sup> <https://www.masimo.com/company/news/news-media/#2c48b39a-5aba-4950-8096-305881a036f2>

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**PUBLIC INTEREST STATEMENT OF NON-PARTY  
PATIENT SAFETY MOVEMENT FOUNDATION**

My name is Michael A.E. Ramsay, MD, FRCA, and I am the Chief Executive Officer of the Patient Safety Movement Foundation (“PSMF”). I have served on the board of PSMF since 2013. I am also Chairman Emeritus of the Department of Anesthesiology and Pain Management at Baylor University Medical Center in Dallas, Texas, and I serve as a member of the Baylor University Medical Center Board of Trustees.

As the Past Director of Anesthesia for the liver transplant program at Baylor, I have personally provided anesthesia for over 1,000 transplant recipients. As part of my prior practice, I first learned about Masimo’s life-changing technologies. I was privileged to meet Masimo’s founder, Joe Kiani, soon after he founded Masimo. I was impressed with his tremendous drive to create technology that will make our healthcare systems safer. In 2014, Joe continued these efforts by creating the Patient Safety Movement Foundation, a non-profit aimed at reducing the 200,000 preventable deaths in U.S. hospitals each year to zero. I now lead that organization. We aim to achieve zero preventable patient harm and death across the globe by 2030.

On behalf of PSMF, I write in support of the recommended orders in the Commission’s investigation regarding Apple’s unfair importation of watches containing pulse-oximetry functionality. PSMF believes that devices like the Apple Watch, which do not offer hospital-grade pulse oximetry functionality, are potentially dangerous to the public, particularly given Apple’s historic marketing of the feature. Consumers will believe based on this advertising that the Apple Watch will provide them with accurate and clinically relevant information. This is especially true given Apple’s public perception as a technology giant. If Apple says the device measures blood oxygen saturation, most consumers will not question that.

The Apple Watch Series 6 was launched in Fall of 2020 in the midst of the COVID-19 pandemic. Reports suggested starting in 2020 that COVID-19 had a fairly significant effect on the

body's ability to oxygenate blood.<sup>1</sup> This led to sales of fingertip pulse oximeters increasing 500% during a single week in February 2020 and by mid-May the devices were sold out in many stores.

*Id.*

Apple's launch of the Series 6 capitalized on this market demand even though it was not clinically validated.<sup>2</sup> Apple's launch video featured Dr. Sumbul Ahmad Desai, MD, the VP of Health at Apple. In the video she was asked to talk "about blood oxygen and its importance to your health." *Id.* at 2:36-2:42. She stated:

Blood oxygen saturation also known as SpO<sub>2</sub> is like a vital sign. It's a key measurement that contains critical information about your breathing and circulation. Apple Watch is already a powerful health tool with apps that measure heart rate and hear rhythm and now adding blood oxygen brings another valuable health measurement to users. Blood oxygen and pulse oximetry are terms that we've heard a lot about during the COVID pandemic. As you breathe your heart and lungs work together to deliver oxygen throughout your body. Blood oxygen saturation is an indication of how well this system is functioning and of your overall respiratory and cardiac health and pulse oximetry is how you measure it.

*Id.* at 2:42-3:28

Apple's touting of the device during the COVID pandemic, despite the lack of validation as providing clinically meaningful data to patients, posed a risk to any individual who sought to use the device as a way of protecting themselves from the adverse consequences of COVID. The risk is highlighted by Masimo's recent White Paper related to its Masimo W1 healthwatch that contains a study comparing the Masimo W1 to the pulse oximeter in the Apple Watch Series 7.<sup>3</sup>

As shown in Table 6 of the White Paper—reproduced below, the Adjusted ARMS for the

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<sup>1</sup> [https://www.washingtonpost.com/lifestyle/wellness/pulse-oximeter-covid-19-coronavirus/2020/05/18/5b6f8a98-96df-11ea-9f5e-56d8239bf9ad\\_story.html](https://www.washingtonpost.com/lifestyle/wellness/pulse-oximeter-covid-19-coronavirus/2020/05/18/5b6f8a98-96df-11ea-9f5e-56d8239bf9ad_story.html)

<sup>2</sup> <https://www.youtube.com/watch?v=YKQFaPRObp8>

<sup>3</sup> [https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A\\_Whitepaper\\_Masimo\\_W1\\_US\\_v4.pdf?v=1670952306](https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A_Whitepaper_Masimo_W1_US_v4.pdf?v=1670952306)



Apple Watch was below that required for FDA clearance, while the Masimo W1 achieved results at a hospital-grade level.

**Table 6.** Tabulated Summary of Performance Statistics for Masimo W1 and Apple Watch

	Bias (%)	Precision (%)	ARMS (%)	Adjusted Precision (%)	Adjusted ARMS (%)
Masimo W1	0.2	1.5	1.5	1.6	1.6
Apple Watch	3.1	3.2	4.4	3.4	4.6

Moreover, unlike the Apple Watches with pulse-oximetry functionality, the Masimo W1 offers continuous monitoring of SpO<sub>2</sub>. This is incredibly important. Rapid blood-oxygen desaturations are a serious problem and often occur when someone is sleeping. For example, it can occur because of sleep apnea. Masimo's study indicates the Masimo W1 successfully "catches" these dips in oxygen saturation, while the Series 7 barely functions due to its non-continuous monitoring and its need to be positioned perfectly. This is shown in Table 7 of the White Paper reproduced below:

**Table 7.** Tabulated Summary of Fast Desaturation Events and Detection Rates for Masimo W1 vs Apple Watch

Test Configuration	Number of Subjects	Number of Valid Events	Detection Rate for Masimo W1	Detection Rate for Apple Watch
Configuration 1	7	49	49/49=100%	3/49=6.1%
Configuration 2	8	60	60/60=100%	4/60=6.7%

Detection Rate = (Nt / Ndesat) x 100 (%), Nt = Number of Detected Event by Test Device, Ndesat = Number of All Valid Fast Desaturation Events by Reference SpO<sub>2</sub>

In my opinion, this data indicates that the blood oxygen sensor in the Apple Watch does nothing beneficial for the public welfare.

It is also not clear that any of the other features of the Apple Watch offer a net benefit to the public health. Although I have read anecdotal reports of people with Apple Watches believing it led to them getting checked out for a heart issue or it contacted authorities after a crash, it is not clear whether these beneficial incidents are merely random or that they justify the significant false

positives. To the extent the watch is alerting authorities when there is no danger or sending users to emergency rooms when they are perfectly healthy, there is a huge societal cost.

It is my understanding that the Apple Watch has been criticized for these false positives with respect to numerous of its apps. For example, a recent article in the New York Times criticized the crash detection features and indicated it was creating a heavy burden on 911 operators in certain parts of the country.<sup>4</sup> The Journal of the American Medical Informatics Association, also published a study concluding that false positives from the Apple Watch “may lead to overutilization of healthcare resources.”<sup>5</sup> The study concluded “The Food and Drug Administration and Apple should consider the unintended consequences of widespread screening for asymptomatic (“silent”) atrial fibrillation and use of the Apple Watch abnormal pulse detection functionality by populations in whom the device has not been adequately studied.” *Id.*

The cost of a “false positive,” is difficult to calculate. A single errant 911 call might only cost a small amount of an operator’s time. But, it could also lead to first responders being unavailable to provide life-saving treatment to an actual crash victim. There is also the emotional toll of a patient believing they have a serious heart condition, only to find out it was false.

A broken clock might be right twice a day, but when caring for patients you need a clock that works. That is what PSMF seeks to achieve in healthcare, and that is what Masimo’s innovations have helped the healthcare industry move to. I fear that investment in these life-saving technologies might cease if companies like Apple are allowed to infringe the intellectual property rights of innovative companies like Masimo without consequence. It is in the public interest to protect these creators and accordingly, an exclusion order will benefit the public welfare and

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<sup>4</sup> <https://www.nytimes.com/2023/02/03/health/apple-watch-911-emergency-call.html>

<sup>5</sup> <https://academic.oup.com/jamia/article/27/9/1359/5911974?login=false>

further PSMF's goals to rid the world of preventable medical errors.

Best regards,

A handwritten signature in dark ink, appearing to read "Michael Ramsay MD". The signature is fluid and cursive, with the letters "M", "R", and "M" being prominent.

Michael Ramsay, MD

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**PUBLIC INTEREST STATEMENT OF NON-PARTY BOBBY YAZDANI**

My name is Bobby Yazdani, and I write to support an exclusion order in this matter because it will further U.S. innovation and support entrepreneurs at every level, from the innovator starting a company in his garage to Fortune 500 companies. Denial of an exclusion order will incentivize big technology companies such as Apple to infringe on the intellectual property rights. Innovators will not have protection to encourage their innovations if an infringer can be excused when the infringement becomes pervasive in the U.S.

I am the founder and partner of Cota Capital, a San Francisco-based firm investing primarily in private and public U.S.-based technology companies. Healthcare is one area of focus for Cota Capital investments. Cota Capital has invested in early-stage and growth healthcare companies such as Activ Surgical, Bioniz, Blueprint Genetics, CellFE, Correlia Biosystems, Excision Biotherapeutics, Guardant Health, Mission Bio, Purigen Biosystems, and Vave Health. At the heart of any healthcare company's business and product strategy is its ability to protect its intellectual property. Before investing in a healthcare company, Cota Capital's due diligence involves a careful assessment of the company's existing and potential intellectual property. Cota looks for companies able to build strong intellectual property to protect their innovation along with Cota's investments. Without the ability to exclude others, companies risk others freely copying their innovations, and funding will not be available.

### **Masimo Is A Leader In Innovation**

Masimo was one of the first, albeit quite small, investments I made in 1991. I have watched Masimo grow and flourish from its humble beginnings to the leader in noninvasive monitoring. Masimo is a stunning example of the fortitude and progress American innovators bring to address hard scientific and societal problems when given the resources and tools.

Decades ago, the medical device industry was plagued with an inability to measure blood oxygen saturation while the patient was moving or had low blood flow. The industry had abandoned solving the problem. Masimo persevered and solved the "unsolvable" problem, creating the first monitor that could accurately measure blood oxygen saturation during these difficult conditions. Rather than partner with Masimo, many companies in the industry copied Masimo's technology. Masimo asserted its intellectual

property rights against the then industry giants. Multiple courts upheld Masimo's patents, finding those industry giants, such as Nellcor (now part of Medtronic) and Philips, infringed Masimo's patents.<sup>1</sup> Today, Masimo's noninvasive monitoring technologies are used to monitor over 200 million patients annually.<sup>2</sup> Masimo's strong intellectual property portfolio protecting its innovations from infringers have been crucial to its development of further innovation.

From its inception, Masimo has strived to improve the health and wellness of patients worldwide. Masimo continues to invest and innovate to keep patients safe and healthy. Masimo has expanded to bring its hospital-grade products directly to consumers. Masimo's latest consumer product offering is the Masimo W1 watch, which monitors blood oxygen saturation, hydration, pulse rate, pulse rate variability, heart rate, respiration rate, and other parameters.<sup>3</sup> Masimo does not release aspirational products, but rather quality products that accurately monitor vital signs with hospital-level accuracy.

#### **Apple's Behavior Sets A Dangerous Precedent That Must Be Stopped**

Large technology companies engage in "efficient infringement" because the illegitimate practice is cheaper than licensing the IP from smaller competitors. I understand that Apple met with Masimo in 2013 claiming a desire to integrate Masimo's technology into Apple products. Rather than obtain genuine Masimo technology legitimately from Masimo, Apple began systemically hiring Masimo's employees, including key executives at Masimo Corporation and its sister company, Cercacor Laboratories. I was disappointed when I learned that Apple was using Masimo's patented technology. Sadly, this behavior is not new. Apple has previously met with innovative companies and later integrated that same

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<sup>1</sup> Philips Electronics Loses \$467 Million Patent Verdict to Masimo, Reuters, <https://www.reuters.com/article/usphilips-masimo-verdict/philips-electronics-loses-467-million-patent-verdict-to-masimoidUKKCN0HQ54W20141001>; Nellcor and Masimo Corporation Announce Settlement of Patent Litigation, BioSpace, <https://www.biospace.com/article/releases/nellcor-and-masimo-corporation-announce-settlement-of-patent-litigation-/>

<sup>2</sup> <https://www.masimo.com/company/masimo/about/>

<sup>3</sup> <https://www.masimopersonalhealth.com/products/masimo-w1>

technology into their products.<sup>4</sup> Apple has engaged in this type of efficient infringement for years.<sup>5</sup> Efficient infringement is Apple's practice of infringing patents because the reward of infringement is greater than the risk.<sup>6</sup> Efficient infringement calculates that the company may never have to pay for the technology or will have to pay less if litigated in court. This practice is counter to the ethos of our U.S. patent system and should not be tolerated.

**Excluding Apple's Infringing Products Upholds The U.S. Patent System And Fosters Innovation**

The next step to exclude Apple's infringing products is critical and will confirm that protecting intellectual property remains important, just as those rights were provided by the U.S. Constitution. An exclusion order in this matter is critical in strengthening the U.S. patent system and supporting the U.S. innovation ecosystem. If companies are permitted to infringe and not face exclusion, investments in emerging U.S. technologies will slow. Innovative U.S. companies will not receive the financial backing necessary to bring their technologies to the public. The public in turn will suffer as they will miss out on these technologies. As a venture capital firm, Cota Capital relies upon the U.S. patent system to protect its investments. If Cota Capital cannot do so, it will have to reconsider its investment strategy, thereby harming U.S. innovation and the public interest.

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<sup>4</sup> Apple Accused of Stealing Dual-Camera Technology Used In Latest iPhones, <https://appleinsider.com/articles/19/08/15/apple-accused-of-stealing-dual-camera-technology-used-in-latest-iphones>; *Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*, Inv. No. 337-TA-1266 (Alive-Cor Investigation).

<sup>5</sup> Apple Pays for Its Patent Infringement, But Important Legal Cases Continue, <https://ipwatchdog.com/2019/03/19/apple-pays-patent-infringement-important-legal-cases-continue/id=107425/>

<sup>6</sup> The Trouble With Patent-Troll-Hunting, The Economist, [https://www.economist.com/business/2019/12/14/the-trouble-with-patent-troll-hunting?utm\\_medium=cpc.adword.pd&utm\\_source=google&ppccampaignID=17210591673&ppcadID=&utm\\_campaign=a.22brand\\_pmax&utm\\_content=conversion.direct-response.anonymous&gclid=Cj0KCQiA3eGfBhCeARIsACpJNU\\_cf-PjW0-CNCj\\_Ig0lsTA39ZQBEPmJZqyZ88qyXmfzDKPaW2-gwaAkJPEALw\\_wcB&gclsrc=aw.ds](https://www.economist.com/business/2019/12/14/the-trouble-with-patent-troll-hunting?utm_medium=cpc.adword.pd&utm_source=google&ppccampaignID=17210591673&ppcadID=&utm_campaign=a.22brand_pmax&utm_content=conversion.direct-response.anonymous&gclid=Cj0KCQiA3eGfBhCeARIsACpJNU_cf-PjW0-CNCj_Ig0lsTA39ZQBEPmJZqyZ88qyXmfzDKPaW2-gwaAkJPEALw_wcB&gclsrc=aw.ds); Online Platforms and Market Power Part 6: Examining the Dominance of Amazon, Apple, Facebook, and Google, Questions for the Record from the Honorable Henry "Hank" Johnson, Jr. <https://docs.house.gov/meetings/JU/JU05/20200729/110883/HHRG-116-JU05-20200729-QFR059.pdf>.

Small innovators will be particularly harmed by denying an exclusion order. Small innovators have limited resources and will be unable to secure funding for their ideas if large companies like Apple, with unlimited resources to litigate, can steal with impunity or tie up such disputes for years in the courts. Unique perspectives from everyday U.S. citizens push innovation forward. The small inventor may be the one who develops life-saving technologies that impact millions. Without the ability to secure funding, these life-saving technologies will never be brought to the public.

The pervasiveness of a company's infringement does not excuse its. The Commission should not entertain an argument that the public likes or pervasively uses the Apple Watch. This rewards infringement by large companies who have the resources to infringe others' technology, widely distribute it to U.S. citizens and then litigate as long as possible. The volume of Apple Watch sales is not a free pass for Apple to infringe upon the intellectual property rights of others. Also, Apple's watches come from outside the U.S., such as from China, being made in factories with reportedly deplorable working conditions. The Masimo W1 is manufactured in the United States.

Apple has endless resources to crush innovative companies in the legal system and stall enforcement. Apple's practice of meeting with innovative companies and hiring their key talent to gather the companies' intellectual property indirectly should be stopped. The public interest is best served by upholding intellectual property rights and stopping infringers like Apple.

#### **Devices That Monitor Blood Oxygen Saturation And Other Apple Watch Models Remain**

U.S. consumers will continue to have access to comparable or better technologies than in the excluded Apple Watches. I understand that this investigation sought exclusion of Apple Watch models that offer the ability to measure blood oxygen saturation, including the Apple Watch Series 6, 7, 8, and Ultra. Apple offers other that do not measure blood oxygen saturation, including the Apple Watch SE. Thus, not all models of the Apple Watch will be excluded if the Commission upholds the Initial Determination's recommendation to exclude these models of the Apple Watch. U.S. consumers may still



obtain imported an Apple Watch SE.<sup>7</sup> Apple could also choose to respect others intellectual property, and simply remove the infringing sensor.

Moreover, the public will still have options to monitor blood oxygen saturation at the wrist. The Masimo W1 offers clinical-grade blood oxygen saturation not available in the Apple Watch. The Masimo W1 provides continuous monitoring of a user's blood oxygen saturation while the Apple Watch can only take spot measurements, i.e., a one-time measurement sporadically. The Apple Watch is also limited in only measuring blood oxygen saturation when the watch is completely motionless and in a constraint orientation.<sup>8</sup> In contrast, the Masimo W1 continuously measures blood oxygen saturation in any orientation, including while the user is moving.<sup>9</sup> Thus, consumers have a superior option to monitor blood oxygen saturation with Masimo's product offering.

I respectfully urge the Commission to uphold the intellectual property of innovators, such as Masimo.

Sincerely,



Bobby Yazdani

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<sup>7</sup> <https://www.apple.com/apple-watch-se/>

<sup>8</sup> <https://support.apple.com/guide/watch/blood-oxygenapdaf17aa5ef/watchos>

<sup>9</sup> [https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A\\_Whitepaper\\_Masimo\\_W1\\_US\\_v4.pdf?v=1670952306](https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A_Whitepaper_Masimo_W1_US_v4.pdf?v=1670952306)

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**PUBLIC INTEREST STATEMENT OF NON-PARTY MITCHELL GOLDSTEIN, MD**

My name is Mitchell Goldstein, M.D. I am submitting this response to the Commission's solicitation of comments on public interest issues raised by the ALJ's recommendations for relief in Investigation No. 337-TA-1276. In my view, the recommended relief is in the public interest, given the strong public interest in incentivizing investment into innovations that protect life-changing and life-saving technologies, such as those developed by Masimo. In contrast, the use of devices such as the Blood Oxygen feature in Apple Watches since the release of the Series 6, which does not include medical-grade technology for continuous measurement of oxygen saturation levels, damages public health and welfare. This is because consumers and even physicians commonly, but incorrectly, assume that pulse oximeters are all the same and that this feature is, therefore, is capable of generating reliable blood oxygen measurements for medical use.

I am a neonatologist in Southern California. I am affiliated with a number of hospitals, including Loma Linda University Medical Center in Loma Linda, CA, and Queens of the Valley Hospital in West Covina, CA. I am also a professor of Pediatrics in the Neonatology Division at Loma Linda University. Since 2018, I have been the Editor-in-Chief of Neonatology Today, the only peer-reviewed monthly newsletter available free to neonatologists, perinatologists, neonatal nurses, neonatal respiratory care specialists, parents, and anyone else interested. I write extensively on neonatology issues, including the use of pulse oximetry. I obtained my medical degree from the University of Miami, completed my residency at the University of California Los Angeles, and completed a fellowship at the University of California Irvine.

Patient care and consumer health both depend on the availability of equipment designed specifically to meet clinical accuracy. In my experience, Masimo is a true innovator in the field of medical devices, such as non-invasive physiological monitoring, and has significantly contributed to public welfare by providing its cutting-edge technology to the public. I was first referred to

Masimo in the early 1990s after coming to understand that other pulse oximeters, even sold to hospitals, did not properly work on neonates.<sup>1</sup> This was a significant concern for neonatologists because the risk of severe retinopathy of prematurity (ROP) in preterm newborns is caused by high oxygen levels during the first few weeks after birth and low oxygen levels at later postmenstrual ages.<sup>2</sup> ROP is the second leading cause of blindness in childhood in the United States, and it has been known for over 50 years that excessive oxygen in the first few weeks of postnatal life is a major risk factor for ROP.<sup>3</sup> Accurate measurement of oxygen in premature infants also impacts treatment decisions for many other conditions.

During my training and early practice as a neonatologist, pulse oximeters (devices designed to measure the amount of oxygen in the blood) had been more than a casual annoyance. The incessant beeping and alarming of the non-functional devices were more of a distraction than a useful clinical tool. During one outbreak of retinopathy of prematurity, an associate of mine went through the neonatal intensive care unit, shutting off every oximeter in the room. These poorly performing pulse oximeters were the cause of inappropriate oxygen administration. Several weeks later, I discussed our frustration with a manufacturer of newborn hospital equipment and expressed my concern that no one in the field was working to enhance the state of the art. He gave me the contact numbers for Masimo. This began my interest in their technology.

Since 1994, I have been involved in clinical studies with Masimo Signal Extraction Technology (SET) pulse oximeters. My early studies demonstrated the practicality of a “Novel Pulse Oximeter Technology Resistant to Noise Artifact and Low Perfusion” and that this

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<sup>1</sup> A more detailed accounting of my experience with Masimo technology is available from my prior testimony before the Senate Judiciary Committee.

[https://www.judiciary.senate.gov/imo/media/doc/goldstein\\_testimony\\_04\\_30\\_02.pdf](https://www.judiciary.senate.gov/imo/media/doc/goldstein_testimony_04_30_02.pdf)

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4016714/>

<sup>3</sup> *Id.*

technology was “...Capable of Reliable Bradycardia (low heart rate) Monitoring in the Neonate”. Subsequently, I demonstrated a 90% reduction in false alarms in neonatal patients using Masimo technology. I showed that “Conventional Pulse Oximetry Can Give Spurious Data in a Neonatal Population at Risk for Retinopathy of Prematurity (ROP)” demonstrated the feasibility of reliable pulse oximetry operation during neonatal transport and revealed that Masimo SET reliably tracks neonatal heart rate variability. We investigated and concluded that “Selective Inattention to Pulse Oximetry Alarms is Unsafe in Infants at Risk for Apnea of Prematurity.” In studying the competitor Nellcor’s alarm management technology, SatSeconds™, we showed that in an effort to limit “nuisance” alarms, the Nellcor N-395 misses relevant desaturations and jeopardizes the detection of the infant at risk for sudden infant death syndrome.

Masimo’s technology significantly reduced errors in calculating the blood oxygen levels in neonates, saving countless individuals from a lifetime of eye damage and even blindness. Clinical studies have established the success of Masimo’s SET Technology, showing a strong positive association between the use of Masimo SET pulse oximetry with a reduction in the incidence of ROP.<sup>4</sup>

Masimo’s commitment to serving the neonate population via its innovative technology is essential to positive outcomes, and even the other hospital-focused pulse oximetry companies were not innovating to solve the problems we were experiencing with pulse oximetry. Masimo’s commitment to innovation for the neonatal population is even more impressive given the relatively low population of neonate patients compared to adult patients and, therefore, the lack of a substantial commercial reason to commit resources to this specific population. For years I had to make do with inaccurate pulse oximeters made for adults in our neonate populations, leading to

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<sup>4</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1651-2227.2010.02001.x>

ROP issues. Masimo changed this by providing innovative technology and products made especially for this incredibly vulnerable population. It is essential to the health and welfare of all Americans that we continue to incentivize innovation through a strong intellectual property system and discourage infringement. Without such protections, companies such as Masimo will lose financial incentives for assisting underserved patient populations with innovative technologies.

In contrast to Masimo’s cutting-edge technology, the oxygen saturation measurement feature found in the Apple Watch does little, if anything, to aid the health and welfare of the public.<sup>5</sup> Apple recognizes that its blood oxygen measurements are “not intended for medical use and are only designed for general fitness and wellness purposes.”<sup>6</sup> But, pulse oximetry is an essential medical measurement, sometimes considered the “fifth vital sign.” Apple does not show in its commercial advertising—except in the small print—that its pulse oximetry feature is not medically useful. I have met physicians who believe the Apple Watch must contain medical-grade pulse oximetry technology simply because it is sold by Apple and advertised as a beneficial health feature. Yet numerous commentators have written about the inaccuracy of the Apple Watch’s measurements.<sup>7</sup> The incorrect perception that Apple’s pulse oximetry feature includes reliable technology could lead to both false positives and false negatives, hurting the public welfare.

### **The Recommended Remedies Support Healthcare Innovation**

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<sup>5</sup> Because the pulse oximetry feature of the Apple Watch is only for those over the age of 18 it certainly has no benefit for the underserved neonate population who benefit from Masimo’s innovation.

<sup>6</sup> <https://support.apple.com/en-us/HT211027>

<sup>7</sup> <https://www.washingtonpost.com/technology/2020/09/23/apple-watch-oximeter/> (article entitled “The new Apple Watch says my lungs may be sick. Or perfect. It can’t decide.”); <https://www.medpagetoday.com/opinion/skeptical-cardiologist/88729> (“If you are primarily excited by the oxygen sensing capabilities of [Apple Watch Series 6] I would recommend instead purchasing a \$20 finger tip pulse oximeter.”)

Providing companies with appropriate relief at the ITC is essential to protect American innovation. A conclusion otherwise would encourage infringement by Apple and others and would disincentivize innovation. This will dramatically impact smaller companies that do not have the resources to compete unless they can protect their innovations. I believe the public's interest in encouraging investment in health technology innovation outweighs any potential public interest in Apple's continued infringement.

Sincerely Yours,

Dated: February 24, 2023



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**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of  
CERTAIN LIGHT-BASED  
PHYSIOLOGICAL MEASUREMENT  
DEVICES AND COMPONENTS  
THEREOF**

**Investigation No. 337-TA-1276**

**STATEMENT OF NON-PARTY  
AMERICAN HEART ASSOCIATION  
ON THE PUBLIC INTEREST OF THE RECOMMENDED REMEDIAL ORDERS  
BUT NOT IN SUPPORT OF ANY PARTY**



## **I. INTRODUCTION**

The American Heart Association, Inc. (the “AHA”) believes the ALJ’s recommended remedial orders would harm scientific research, healthcare consumers, and healthcare providers in the U.S. Accordingly, the AHA urges the Commission to tailor any remedial orders to allow researchers adequate time to complete ongoing research projects and transition to new protocols with devices not subject to any limited exclusion order (“LEO”) or cease and desist order (“CDO”).

## **II. AHA’S INTEREST IN THE RECOMMENDED REMEDIAL ORDERS**

As the nation’s oldest and largest voluntary health organization, the AHA strives to be a relentless force for a world of longer, healthier lives with a particular emphasis on a broad-range of cardiovascular and stroke-related health topics. Working at the intersection of science and technology is the AHA’s Center for Health Technology and Innovation (“CHTI”), which encourages the use of digital health solutions to lower healthcare costs, increase patient engagement and improve healthcare outcomes for patients and consumers. The AHA and the CHTI fund vital scientific research, bringing together research institutions, technology and digital health companies in research programs seeking new applications of technology to improve overall consumer well-being and to provide affordable preventive, diagnostic and treatment measures.

The AHA has a research relationship with the Respondent in the Investigation. It has no position on the merits of the investigation and supports none of the private parties. However, we are concerned about the direct, harmful, near-term impact that the recommended LEO and CDO would have on healthcare consumers, healthcare providers and scientific researchers in the U.S.

We understand the ALJ’s recommends an LEO with a standard certification provision and a CDO with respect to Apple Watch Series 6, 7, and certain prototype products referred to as Next Generation (“Devices”). The Devices play a unique role in research of interest to the AHA and healthcare consumers. As prevalent consumer devices owned for reasons other than just their cardiac-data-related technologies, the user population is sufficiently large and representative of the

subjects researchers seek to recruit, that they allow studies to be fully enrolled cost-effectively, facilitating research the AHA promotes. Additionally, the Devices and their users allow for types of research to occur that might not otherwise be attempted, or only attempted less frequently or with smaller sample sizes. Notably, they facilitate research into whether cardiac health outcomes can be improved by consumer devices detecting and triggering interventions. As the novelty of these devices has waned since their introduction, researchers benefit from and, to some extent, rely on the extent of consumer adoption of the Devices to design and recruit for research studies.

### **III. THE RECOMMENDED REMEDIAL ORDERS JEOPARDIZE CARDIOVASCULAR AND OTHER SCIENTIFIC RESEARCH**

The AHA encourages the development and proliferation of reliable consumer healthcare devices that assist patients and healthcare consumers in better understanding and managing their own health and well-being, in communicating with their healthcare providers, and participating in valuable and decentralized health research. Our aim is to build new types of healthcare insights to improve our understanding of how technology-based devices and solutions can best impact care.

#### **A. The Devices Provide Important Data Acquisition and Reporting Technology For Basic Scientific Research by Numerous Researchers**

The AHA is currently collaborating on two research studies involving Apple Watches, one is a Vanderbilt University study related to Atrial Fibrillation (“AF”)<sup>1</sup> and the other a Johns Hopkins University study related to Coronary Artery Disease and cardiac rehabilitation.<sup>2</sup> These studies utilize data obtained from study participants while wearing Apple Watches, including the Devices. Other institutions are involved in similar research. Data available from the website ClinicalTrials.gov indicates there are several U.S. clinical trials that are currently active, recruiting,

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<sup>1</sup> See [https://clinicaltrials.gov/ct2/show/NCT04433091?term=%22Apple+Watch%22+AND+%28%22series%22+OR+%22ECG%22%29&recrs=abdf&map\\_centry=US&draw=2&rank=8](https://clinicaltrials.gov/ct2/show/NCT04433091?term=%22Apple+Watch%22+AND+%28%22series%22+OR+%22ECG%22%29&recrs=abdf&map_centry=US&draw=2&rank=8).

<sup>2</sup> See <https://clinicaltrials.gov/ct2/show/NCT05238103?term=%22Apple+Watch%22&recrs=abdf&centry=US&draw=4&rank=30>.

or planned involving various Apple Watch Series, including the Devices.<sup>3</sup> These include ECG studies by Yale University<sup>4</sup> and the Mayo Clinic;<sup>5</sup> a hypertension study by Stanford University;<sup>6</sup> an AF study by the University of Oklahoma;<sup>7</sup> and two heart failure studies by Biofourmis Singapore Pte Ltd.<sup>8</sup> and by Tufts Medical Center.<sup>9</sup> The AHA believes these studies utilize Device features other than the pulse oximetry feature at issue in the investigation; however, the ALJ's recommended remedial orders would nonetheless impact usage of the Devices in these studies.

The Devices provide a combination of clinically-interesting technological features and ongoing consumer prevalence *in a single wearable* that makes them a very attractive research platform. Additionally, an aim of some of that research is to investigate if consumer health can be improved via data from a consumer-worn device, such as the Devices, prompting interventions through the device or otherwise. The AHA is not aware of alternative devices available in volume in the U.S. that provide the same combination of attributes to researchers and consumers.

**B. Requiring Researchers to Change Devices Would Jeopardize the Scientific Merit of Ongoing and Past Research and Waste Investments Made**

Clinical and other scientific research requires months or years of planning, including design of research protocols and study objectives, interaction with governing bodies and collaborators,

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<sup>3</sup> See <https://clinicaltrials.gov/ct2/results?cond=&term=%22Apple+Watch%22&cntry=US&state=&city=&dist=&Search=Search&recrs=a&recrs=b&recrs=d&recrs=f> (last visited 2/21/2023).

<sup>4</sup> See <https://clinicaltrials.gov/ct2/show/NCT04468321?term=%22Apple+Watch%22+AND+%28%22Series%22+or+%22atrial%22%29&recrs=abdf&draw=2&rank=4>.

<sup>5</sup> See [https://clinicaltrials.gov/ct2/show/NCT05324566?term=%22Apple+Watch%22+AND+%28%22series%22+OR+%22ECG%22%29&recrs=abdf&map\\_cntry=US&draw=2&rank=1](https://clinicaltrials.gov/ct2/show/NCT05324566?term=%22Apple+Watch%22+AND+%28%22series%22+OR+%22ECG%22%29&recrs=abdf&map_cntry=US&draw=2&rank=1).

<sup>6</sup> See <https://clinicaltrials.gov/ct2/show/NCT03893500?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=3&rank=12>.

<sup>7</sup> See <https://clinicaltrials.gov/ct2/show/NCT05172765?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=4&rank=28>.

<sup>8</sup> See <https://clinicaltrials.gov/ct2/show/NCT04191356?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=5&rank=38>.

<sup>9</sup> See <https://clinicaltrials.gov/ct2/show/NCT04510779?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=2&rank=2>.

enrolling subjects, and procuring necessary materials. Significant investment of time, money, and other resources have been made in the research involving the Devices in which the AHA has been involved, and we believe in other research.

For ongoing studies that are recruiting or those that have already been designed involving the Devices, the recommended remedial orders could jeopardize their scientific merit and cause waste of resources spent for the studies. Of course, the design of research protocols seeks to control for extraneous influences. If Apple Watch data in ongoing research could no longer be obtained because new participants had to use different devices as a result of the LEO or CDO, then questions about comparability of data before and after the device change likely would arise, if it were even possible to continue the study. This risks loss of some or all of the statistical power of gathered data and resulting scientific merit of the study. Studies planned for extended periods (the Vanderbilt study, for example, lists a 4 year time frame through May 2024) will likely be negatively impacted by a remedial order requiring switching mid-study to a new device. Similarly, for studies that have been designed, funded, and are recruiting now, or nearly so, switching devices risks requiring re-design of the study and waste of resources expended to date.

#### **IV. THE COMMISSION SHOULD TAILOR ANY REMEDIAL ORDERS TO ALLOW FOR ONGOING RESEARCH AND CONSUMER ACCESS**

The AHA believes that public interest is best served by keeping any current products on the market that contain electrocardiogram, heart rate monitoring, irregular heart rate notification and supporting features combined in some form. The devices currently on the market with verified accuracy are important to consumers, healthcare providers and researchers involved in assessing the impact of those devices to improve patient understanding, health, and outcomes.

From the AHA's perspective, the Devices are not just a pure technical component used in clinical research. Part of their interest is that they are widely used consumer devices that provide technologies enabling collection and reporting of data of clinical interest. The prevalence of these

devices among consumers not only helps provide research recruits but also helps investigate if a mass consumer device can be used to intervene to improve health outcomes by acquiring data used to (help) detect them. The AHA does not believe that adopting remedial orders requiring certifications by researchers for devices sought to be imported would adequately protect the interests with which it is concerned. *See Commission Opinion (Revised) in Certain Microfluidic Devices*, Inv. 337-TA-1068, at 22–48 (January 10, 2020). As explained above, part of the significance of the Devices is that they are a prevalent consumer device, not just a technical input used by researchers. A standard certification provision included in any LEO issued requiring researchers to indicate that certain Apple Watches sought to be imported were destined for a particular study or trial by certification would not reflect how those devices are used in the type of research the AHA promotes and wishes to see continue and would place a burden on the researchers to undertake the necessary analysis to determine if the certification is proper, further negatively impacting the ability to continue with on-going and already planned research.

For the reasons explained above, the AHA urges the Commission to tailor any remedial orders to ensure the supply of the Devices in the U.S. remain undisturbed over a sufficient time period for ongoing research to be completed and for upcoming research to transition to alternative devices that it expects would be brought to market without significant waste of resources on that research or significant delay in undertaking future research. The AHA believes the time period necessary for that transition to be a year or more.

If it would be helpful to the Commission, the AHA would be happy to provide additional details or information regarding the comments made above.

Date: March 1, 2023

Respectfully submitted,

/s/ Patrick Wayte

American Heart Association, Inc.

Center for Health Technology and Innovation

By and through counsel:

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**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya  
Administrative Law Judge**

**In the Matter of**

**CERTAIN LIGHT-BASED  
PHYSIOLOGICAL MEASUREMENT  
DEVICES AND COMPONENTS  
THEREOF**

**Inv. No. 337-TA-1276**

**DECLARATION OF DR. RICHARD MILANI**

1. My name is Dr. Richard Milani. I am over 21 years of age, of sound mind, and make this declaration voluntarily and based upon my own personal knowledge.

2. I received my M.D. from the University of Florida in 1979. I completed a residency in Internal Medicine at the University of Florida. I then completed fellowships in Critical Care Medicine at the University of Florida, Preventive Medicine and Clinical Epidemiology at Harvard University (Massachusetts General Hospital), and Cardiovascular Diseases at Ochsner Clinic Foundation.

3. I am the Chief Clinical Transformation Officer and Vice Chairman of the Department of Cardiology at Ochsner Health System (“Ochsner Health”). Ochsner Health is an integrated healthcare system with a mission to serve, heal, lead, educate, and innovate. It has more than 34,000 employees, and over 4,500 employed and affiliated physicians in over 90 medical specialties and subspecialties. Ochsner Health operates 40 hospitals and more than 300 health and urgent care centers across Louisiana, Mississippi and the Gulf South, and also serves many patients around the country and world through its digital medicine program. In 2021, Ochsner Health treated more than 1 million people from every state and 75 countries.

4. Since 2012, I have held the role of Chief Clinical Transformation Officer. My responsibilities include developing new methods of healthcare delivery that improve the health of the populations we serve, improve access to care, reduce the cost of care, and reduce the burden on the caregivers of care. To accomplish our goals, we take advantage of new leading edge capabilities that involve both technology as well as artificial intelligence.

5. I understand that Masimo has sued Apple for patent infringement, and that Masimo is seeking to exclude from importation into the United States several generations of Apple Watch that include the Irregular Rhythm Notification (“IRN”), electrocardiogram (“ECG”) App, High Heart Rate Notification (“HHRN”) and Blood Oxygen Sensor (SPO2) functionality.

6. As detailed below, excluding Apple Watch with these features would have major negative implications on public health in this country by greatly hindering patient care and/or medical research in critical areas.



7. The leading cause of death in the United States is chronic disease, ranging from diabetes, to heart disease, to high blood pressure, to Alzheimer's disease. More than 50% of adults in the United States have a chronic disease.<sup>1</sup>

8. About 697,000 people died in the United States from heart disease in 2020; that's 1 in 5 deaths.<sup>2</sup> Heart disease costs the United states about \$229 billion each year.<sup>3</sup>

9. Atrial Fibrillation ("AFib") is the most common type of cardiac arrhythmia. It is often asymptomatic until a major health event occurs, such as a stroke. This is why it is highly valuable to a patient's care to have the ability to track a patient's heart rhythms continuously to check for abnormal rhythms and report such activity to a doctor before a patient experiences a life-threatening medical event such as a stroke. In 2019, AFib was mentioned in more than 183,000 death certificates, and was the underlying cause of death for at least 26,500 people in the United States.<sup>4</sup>

10. Historically, a key challenge for physicians when it comes to treating chronic disease has been a lack of timely and consistent data about the patient's health. Patients often are only seen by a physician a few times per year, and may also only have diagnostic testing associated with their chronic disease performed during those in-person visits. While these appointments and periodic testing provide a useful snapshot about a patient's health, they do not account for medical changes that may be occurring on a monthly, weekly, or daily basis. This applies to heart disease and AFib as well.

11. In 2014, Apple launched HealthKit. HealthKit is a HIPAA-compliant central repository of health and fitness data on Apple Watch. With a user's permission, apps can communicate with HealthKit to access and share this data. Since 2014, HealthKit has been integrated with Epic Systems, a leading provider of electronic medical records in the United States. This integration means that, with a patient's

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<sup>1</sup> About Chronic Diseases | CDC *available at* <https://www.cdc.gov/chronicdisease/about/index.htm#:~:text=Chronic%20diseases%20such%20as%20heart,disability%20in%20the%20United%20States> .

<sup>2</sup> Heart Disease Facts | cdc.gov *available at* <https://www.cdc.gov/heartdisease/facts.htm#:~:text=Heart%20disease%20is%20the%20leadin> .

<sup>3</sup> *Id.*

<sup>4</sup> [https://www.cdc.gov/heartdisease/atrial\\_fibrillation.htm](https://www.cdc.gov/heartdisease/atrial_fibrillation.htm)

permission, health data collected through Apple Watch can be transmitted directly to a patient's electronic medical record and accessible to their physician.

12. Since the launch of HealthKit, Apple has continued to expand the health features that its products track, while software developers have built apps to take advantage of this functionality. These advancements have major benefits when it comes to preventive care because they allow physicians to gather substantially more data about the health of their patients. They also allow physicians to more quickly detect changes in a patient's health, which can lead to earlier detection or deterioration of disease or illness, and can also provide an opportunity for physicians to help prevent catastrophic health events from occurring. This has benefits most importantly for patients, and also reduces the need for hospitalization further reducing healthcare costs. This has included collecting information from patients who have suffered episodes consistent with AFib. At Ochsner Health, we have built healthcare programs around HealthKit to take advantage of this Apple technology. This has led to substantial improvements in blood pressure and diabetes control for thousands of our patients, as well as earlier diagnosis of patients who have AFib from the IRN feature.

13. Indeed, recently, Apple announced a new feature that tracks AFib burden. Ochsner Health is building a management program around this Apple technology, called AFib History, which will give physicians weekly reports about the percentage of time a patient has spent in AFib (termed the "AFib burden") based on data collected from Apple Watch. We expect this to be a program that saves many lives, including by preventing strokes.

14. I am not aware of any comparable wearable product capable of tracking AFib burden. The standard way of monitoring patients with AFib today involves performing EKGs when necessary (which requires a trip to the doctor), sending patients home with a recording device (Holter monitor or single-lead ECG patch) that can be worn for short periods of time (i.e., 24 hours) to monitor and record cardiac activity, or implanting a medical device into a patient's chest through a medical procedure that will record cardiac activity. We expect that the ability to track a patient's cardiac activity daily, by simply having the patient wear an Apple Watch, will revolutionize the way we treat this disease and save many lives.

15. To date, Ochsner has invested approximately \$600,000 into building its AFib Management program. This involves a team of cardiologists, advanced practice providers, Epic software developers and engineers as well as app developers.

16. Another area where Apple's products have allowed for significant preventive medical advancements concerns falling. For those aged 65 and older, falling is a major health concern. Within this population, more than one in four people falls each year, and more than 3 million people are treated in emergency rooms for injuries related to their falls. In 2015, the total medical cost related to falls totaled more than \$50 billion.<sup>5</sup>

17. In 2021, Ochsner Health launched a pilot program related to fall prevention and management called "Connected Stability". This program relies on Apple Watch and iPhone, and has been a huge success among the approximately 350 patients who participated. The program uses fall detection on Apple Watch to detect when a patient falls. Specifically, Apple Watch can detect if a patient falls, and then offers users a chance to indicate through Apple Watch whether they are okay or if there is an emergency. If Apple Watch cannot detect any movement from the user within about one minute of the fall, it will automatically contact emergency services. In addition to this existing functionality, Ochsner has developed its own program through which a healthcare professional from Ochsner will contact a patient for whom Apple Watch has detected a fall to find out if they need any medical assistance (particularly for patients who have fallen but do not believe they need to go to the hospital).

18. For patients that have participated in the pilot program, we have been able to reduce falls by approximately 50%. We have also received incredible feedback from patients about the program. Patients report a tremendous improvement to their quality of life. They report that they are much less worried about falling, and also feel comfort in knowing that they will be able to receive medical assistance quickly if they do fall. We have also found that the 65 and older population is more inclined to wear an Apple Watch consistently than other types of personal emergency response systems (such as existing

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<sup>5</sup> <https://www.cdc.gov/falls/facts.html>.

products where the patient essentially wears an emergency button around their neck). This is because Apple Watch is relatively discrete and is a commonly used product, and it is something that they are not embarrassed to wear. Rather, they are excited to wear an Apple Watch and take advantage of its other functionality.

19. Ochsner has invested approximately \$3 million into its fall prevention pilot program. As mentioned above, more than 350 patients have participated so far. Ochsner plans to roll out this program nationally within the next year. Ochsner currently has more than 20 healthcare professionals working on this program, and we expect those numbers to grow significantly as the program expands.

20. Another feature that would be adversely impacted by the proposed exclusion order is the Apple Watch Blood Oxygen feature. Measuring a person's blood oxygen saturation is an important health and wellness metric, particularly in the midst of the COVID-19 pandemic. Taking this feature out of the hands of consumers would negatively impact the public health and welfare.

21. I am aware that recent medical literature and the FDA has raised concerns about racial bias in existing pulse oximeters. I understand that the disparity shown in the literature is, at least in part, attributed to dark pigments in certain users' skin. I understand that a white paper recently published by Apple identifies steps that Apple took to address this problem when designing the blood oxygen feature.<sup>6</sup> I also understand that in a small-scale study involving the Apple Watch, there were no reported disparities in blood oxygen measurements between those with light and dark skin. Although these results are promising, I believe more research is needed to confirm the findings and assess whether Apple's blood oxygen sensor can take accurate measurements from persons of color.

22. As the above examples demonstrate, Apple is a leading innovator when it comes to healthcare technology. This technology is revolutionizing how we manage our patients. Preventing importation of Apple Watch would be devastating to the progress that is being made every day in this space.

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<sup>6</sup> [https://www.apple.com/healthcare/docs/site/Blood\\_Oxygen\\_app\\_on\\_Apple\\_Watch\\_October\\_2022.pdf](https://www.apple.com/healthcare/docs/site/Blood_Oxygen_app_on_Apple_Watch_October_2022.pdf).

I declare, under penalty of perjury, under the laws of the United States of America, that the foregoing is true and correct.

Executed on March 1, 2023 in New Orleans, LA.

/s/ Dr. Richard Milani

Dr. Richard Milani

Chief Clinical Transformation Officer Ochsner  
Health System

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.**

**In the Matter of**

**CERTAIN LIGHT-BASED  
PHYSIOLOGICAL MEASUREMENT  
DEVICES AND COMPONENTS  
THEREOF**

**Inv. No. 337-TA-1276**

**NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN PART A FINAL  
INITIAL DETERMINATION; REQUEST FOR WRITTEN SUBMISSIONS ON THE  
ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND  
BONDING**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined to review in part a final initial determination (“ID”) of the presiding administrative law judge (“ALJ”), finding a violation of section 337. The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

**FOR FURTHER INFORMATION CONTACT:** Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, D.C. 20436, telephone 202-205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email [EDIS3Help@usitc.gov](mailto:EDIS3Help@usitc.gov). General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on August 18, 2021, based on a complaint filed on behalf of Masimo Corporation and Cercacor Laboratories, Inc., both of Irvine, CA (collectively, “Complainants”). 86 FR 46275 (Aug. 18, 2021). The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,912,501 (“the ’501 patent”), U.S. Patent No. 10,912,502 (“the ’502 patent”), U.S. Patent No. 10,945,648 (“the ’648 patent”), U.S. Patent No. 10,687,745 (“the ’745

patent”), and U.S. Patent No. 7,761,127 (“the ’127 patent”). *Id.* The amended complaint further alleged that an industry in the United States exists and/or is in the process of being established as required by section 337. *Id.* The notice of investigation named Apple Inc. of Cupertino, CA (“Apple”) as a respondent. *Id.* at 46276. The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

Complainants previously withdrew certain asserted claims pursuant to Order No. 25 (Mar. 23, 2022), *unreviewed by* Comm’n Notice (Apr. 12, 2022), and Order No. 33 (May 20, 2022), *unreviewed by* Comm’n Notice (June 10, 2022). Only claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claims 12, 24, and 30 of the ’648 patent, claims 9 and 27 of the ’745 patent, and claim 9 of the ’127 patent remain in the investigation. Claim 18 of the ’745 patent is still at issue for purposes of the domestic industry.

On January 10, 2023, the ALJ issued the Final ID, which found that Apple violated section 337 as to claims 24 and 30 of the ’648 patent, but not as to claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claim 12 of the ’648 patent, claims 9 and 27 of the ’745 patent, and claim 9 of the ’127 patent. *See* Final ID at 335–36. On January 24, 2023, the ALJ issued a Recommended Determination on remedy and bonding (“RD”) should a violation be found in the above-captioned investigation. The RD recommended that, if the Commission finds a violation, it should issue a limited exclusion order directed to certain wearable electronic devices with light-based pulse oximetry functionality and components thereof that are imported, sold for importation, and/or sold after importation by Apple; and a cease and desist order directed to Apple. RD at 2, 5. The RD found the record did not support Apple’s request for an exemption for service and repair. *Id.* at 2-3. The RD additionally recommended that the Commission set a zero percent (0%) bond (*i.e.*, no bond) during the sixty-day period of Presidential review. *Id.* at 6.

On January 23, 2023, Complainants and Apple each filed a petition for review. On January 31, 2023, Complainants and Apple each filed responses to the respective petitions. On February 23, 2023, the parties filed their public interest statements pursuant to 19 CFR 210.50(a)(4). The Commission received numerous comments on the public interest from non-parties.

Having reviewed the record of the investigation, including the Final ID, the parties’ submissions to the ALJ, and the petitions and responses thereto, the Commission has determined to review the Final ID in part. Specifically, the Commission has determined to review (1) the domestic industry with regard to the ’501 patent, the ’502 patent, the ’648 patent, and the ’745 patent; (2) obviousness with regard to the ’501 patent, the ’502 patent, the ’648 patent, and the ’745 patent; (3) written description with regard to claim 28 of the ’502 patent and claim 12 of the ’648 patent; (4) claim construction and infringement with regard to the ’745 patent; and (5) subject matter jurisdiction. The Commission has determined not to review the remaining findings of the Final ID, including the finding of no violation as to the ’127 patent. The Commission notes that on pages 282-83 of the Final ID, in the section entitled “Element[9]: ‘a thermistor,’” the ALJ refers to claim 1 as the independent claim from which claim 9 depends. The Commission understands that reference to be a typographical error and notes that the reference should be to claim 7.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

- (1) What evidence and argument was presented to the ALJ that shows that Complainants were developing, as of the filing of the Complaint, the Masimo Watch and that the Masimo Watch would practice the Poeze and '745 patent claims?
- (2) Should the Commission consider evidence post-dating the Complaint, such as the final design of the Masimo Watch, to establish that Complainants were developing a physical article that would practice the Poeze patents and the '745 patent?
- (3) If the Commission considers the Masimo Watch to be a domestic industry product in the process of being established for the Poeze patents and the '745 patent, what investments and activities should the Commission consider in its analysis?
- (4) What should be considered as a domestic industry product for purposes of an industry in the process of being established – the Rev Sensor products, the Masimo Watch or both? What activities and investments should be considered toward satisfying the domestic industry requirement with respect to that DI product(s)? Was it appropriate to consider investments related to the Circle and Wing Sensors (assuming they are not shown to practice the Poeze patents or the '745 patent prior to the filing of the Complaint) leading to the development of the Rev Sensor products, in finding that a domestic industry exists or is in the process of being established for the Poeze and '745 patents? *See* ID at 301-24. If the Masimo Watch is a DI product for an industry in the process of being established, would it be appropriate to consider activities and investments in products (that themselves do not practice the Poeze patents prior to the filing of the Complaint) that contributed to the development of the Masimo Watch? What investments were made for the Circle sensor, Wing sensor, and Masimo Watch prior to the Complaint being filed and what investments were made after? Should the Commission consider investments made after the Complaint was filed?
- (5) Should recruiting labor expenditures be considered to contribute towards the satisfaction of the economic prong?
- (6) Should executive labor expenditures generally, and executive legal labor expenditures specifically, be considered to contribute towards the satisfaction of the economic prong? How closely does their work have to be connected to the domestic industry product to be included? With respect to the executive labor included in the Final ID's analysis of a domestic industry (*see* ID at 311-313), what evidence shows the extent to which the executives' work was connected to the domestic industry product?
- (7) Is there a statutory basis for considering only certain types of labor expenses with respect to articles protected by the asserted patent for purposes of satisfaction of the domestic industry requirement under section 337(a)(3)(B)?



- (8) Is there a legislative history or caselaw basis for considering only certain types of labor expenses with respect to articles protected by the asserted patent for purposes of satisfaction of the domestic industry requirement under section 337(a)(3)(B)?
- (9) Does Figure 7B in the Poeze Patents show two emitters, each labeled 104, where each emitter has LEDs that can emit light at or about 1610 nm, about 1640 nm, and about 1665 nm? Was Complainants' argument regarding 37 CFR 1.84(p)(4) raised in front of the ALJ, and if not, can the Commission still consider the argument? Is 37 CFR 1.84(p)(4) binding authority on the Commission and does it require the Commission to presume that each emitter set 104 is identical? If so, is that disclosure in Figure 7B sufficient to convey with reasonable clarity to those skilled in the art that, as of the filing date, the inventor was in possession of two sets of LEDs each with "an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength?"

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

In addition, the Commission requests specific briefing to address the following questions relevant to the public interest considerations in this investigation, and responses are encouraged to include evidence in support of their statements:

- (1) Please identify any ongoing or formally planned studies that use the blood oxygen features of the Apple Watches. Should the Commission allow an exemption or delay the effective date of any remedial relief so as to permit importation of the infringing Apple Watches for purposes of conducting such studies? Please explain the rationale and the scope of any such exemption or delay.

- (2) How should the Commission define a reasonable substitute for the infringing Apple Watches?
- (3) Please identify whether any reasonable substitutes for the infringing Apple Watches are available to consumers and whether they are capable of meeting any public health and welfare concerns raised by any remedial relief in this investigation. Is or would there be sufficient supply of any such reasonable substitutes for the infringing Apple Watches? Is the Masimo W1 watch a reasonable substitute and to what extent would supply of these products be available to fill the demand?
- (4) Please explain how easily the infringing features of the Apple Watches could be removed and whether Apple is working on any redesigns with respect to the infringing features and how long implementation of any redesigns would take?
- (5) Is there any production of like or directly competitive products in the United States and how would such production be impacted by any remedial relief?
- (6) Should the Commission include an exemption for repair and/or replacement of broken products impacted pursuant to any potential remedy, and if so, should the exemption only apply under warranty? If a repair and/or replacement exemption is included, should the cutoff date for repair and replacement be the date of the Order or the date the Order becomes final within the meaning of 19 U.S.C. 1337(j)(4)? *See Certain Fitness Devices, Streaming Components Thereof, and Systems Containing Same*, Inv. No. 337-TA-1265, Comm'n Op. at 88-92 (Mar. 23, 2023) (Public Version); *Certain Robotic Floor Cleaning Devices and Components Thereof*, Inv. No. 337-TA-1252, Comm'n Op. at 76-82 (Apr. 13, 2023) (Public Version). Should the exemption apply to products imported prior to the cutoff date or only to products sold to an end user as of the cutoff date? Should the exemption cover only parts for repair, or should it permit replacement of entire units? Please cite and discuss the evidence of record relevant to whether the Commission should include a repair and/or replacement exemption.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

**WRITTEN SUBMISSIONS:** The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the RD by the ALJ on remedy and bonding.

In its initial submission, Complainants are also requested to identify the remedy sought and are requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to identify and explain, from the record, articles that it contends are "components thereof" of the subject products, and thus potentially covered by the proposed remedial orders, if imported separately from the subject products. *See* 86 FR 46275-76. Failure to provide this information may result in waiver of any remedy directed to "components thereof" the subject products, in the event any violation may be found. Complainants are further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on **June 5, 2023**. Reply submissions must be filed no later than the close of business on **June 12, 2023**. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Opening submissions are limited to **100** pages. Reply submissions are limited to **50** pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1276) in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures*, [https://www.usitc.gov/documents/handbook\\_on\\_filing\\_procedures.pdf](https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf)). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on May 15, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR Part 210.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'L.R. Barton', enclosed within a large, loopy circular flourish.

Lisa R. Barton  
Secretary to the Commission

Issued: May 15, 2023

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**COMPLAINANTS' SUBMISSION IN RESPONSE TO THE COMMISSION'S  
MAY 15, 2023 NOTICE OF COMMISSION DETERMINATION TO REVIEW IN PART**

[REDACTED]

domestic industry is found to exist under the statute *whereupon hundreds of Americans lose their jobs* and American companies lose sales and profits in the millions of dollars, all due to illegal foreign competition.

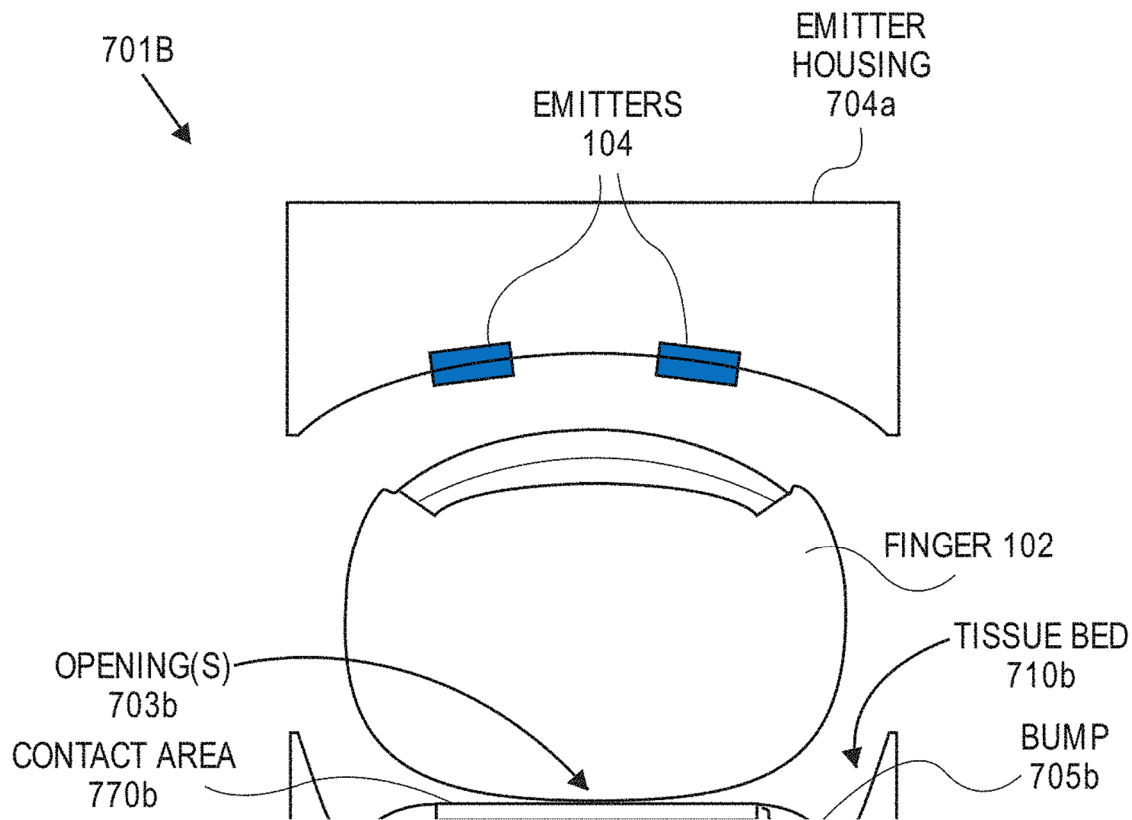
Hearing Before the Subcomm. on Trade of the H. Comm. on Way and Means, 99th Cong. 712-713 (1986) (statement of Donald R. Dinan, Esq., Adduci, Dinan & Mastriani). This is consistent with the language of the statute, which does not specify what types of “labor or capital” qualify so long as they relate to the domestic industry article.

While the Commission has cautioned against crediting investments that “are those of a mere importer,” *see, e.g., Certain In Vitro Fertilization Prods.*, Inv. No. 337-TA-1196, 2021WL 5106055, Comm’n Op at \*10 (Oct. 28, 2021), none of the labor costs relied on by Masimo and credited by the ID could be characterized in such a manner. Accordingly, there is no basis to exclude any domestic labor expenditures relating to the domestic industry articles in this investigation.

**I. Q9: Written Description for ’502 Patent Claim 28 and ’648 Patent Claim 12**

**1. Q9a: Does Figure 7B in the Poeze Patents show two emitters, each labeled 104, where each emitter has LEDs that can emit light at or about 1610 nm, about 1640 nm, and about 1665 nm?**

Figure 7B, as explained by the Poeze Patents’ specification, shows two “emitters,” each labeled with the number 104, and that each emitter has “sets of LEDs” that can emit light at or about 1610 nm, about 1640 nm, and about 1665 nm. Specifically, Figure 7B shows an exemplary sensor 701B with two emitters 104 (highlighted in blue, below):



JX-001 at FIG. 7B (excerpted).

The specification repeatedly describes that each emitter 104 of Figure 7B may include multiple LEDs using different wavelengths. For example, the specification explains that “emitter 104 can include one *or more* sources of optical radiation, such as *LEDs*.” *Id.* at 12:5-9; *see id.* at 26:32 (each emitter “104” includes multiple “LEDs”). It also explains “the emitter may comprise a plurality of LEDs that emit a sequence of pulses of [light] across a spectrum of wavelengths.” *Id.* at 4:55-57. The specification discloses that “emitter 104 can emit [light] at or about 1610 nm, about 1640 nm, and about 1665 nm.” *Id.* at 12:38-40. In that example, emitter 104 would include an LED of a first wavelength (1610 nm), an LED of a second wavelength (1640 nm), and an LED of a third wavelength (1665 nm). The specification describes numerous other examples of emitter 104 with multiple LEDs, each of different wavelengths. *See, e.g., id.* at 12:64-13:1 (“emitter 104 can emit [light]” at eight different wavelengths), 13:5-7 (“emitter 104 can transmit any of a variety

[REDACTED]

of wavelengths of visible or near-infrared optical radiation”), 13:1-5 (“the emitter 104 can emit [light]” within six different wavelength ranges).

Figure 7B includes two such emitters both labeled 104, so the above discussion about the specification applies to *each* emitter 104. That is, for each emitter 104, Figure 7B refers to an emitter with LEDs of multiple wavelengths. And because both emitters in Figure 7B are numbered with the same reference 104, each emitter 104 (made up of multiple LEDs) is presumably the same. *See* 37 C.F.R. § 1.84(p)(4) (“[T]he same reference character must never be used to designate different parts.”; “The same part of an invention ... must always be designated by the same reference character....”); Manual for Patent Examination Procedure § 608.01(g) (“no single reference character [should be] used for two different parts....”) (“MPEP”).<sup>6</sup> Moreover, as discussed below in answering question Q9b regarding the above-cited CFR rule and MPEP section, the Poeze Patents’ specification clearly teaches that the LEDs of the two emitters 104 are the same.

Indeed, the specification refers to each emitter 104 as having “*sets* of LEDs.” Those “sets” describe LEDs of multiple wavelengths. For example, the specification explains that “the emitter 104 can include one or more sources of optical radiation, such as LEDs” and “*sets* of optical sources that are capable of emitting visible and near-infrared optical radiation.” JX-001 at 12:5-12. In that example, emitter 104 includes both an LED configured to emit light at a first wavelength (“visible”) and another LED configured to emit light at a second wavelength (“near-infrared”).

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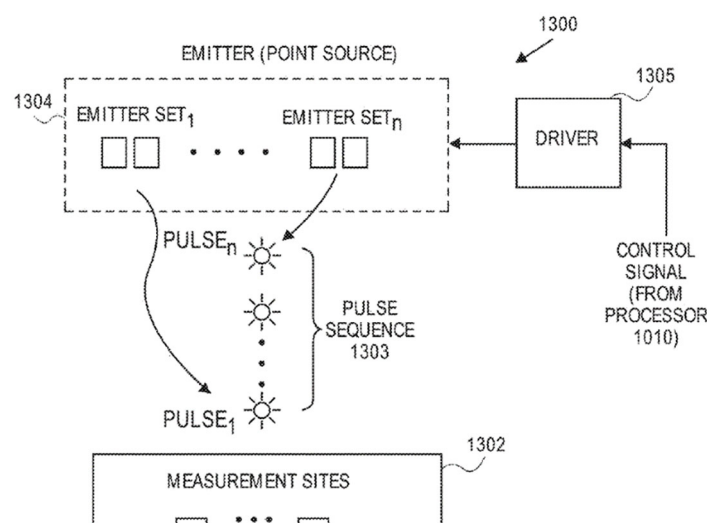
<sup>6</sup> Masimo requests that the Commission take judicial notice of 37 C.F.R. § 1.84(p)(4) and MPEP § 608.01(g).



As another example, the specification teaches that “the emitter 104 can include *sets* of light-emitting diodes (LEDs) as its optical source ... includ[ing] top-emitting LEDs emitting light at about 850 nm to 1350 nm ... [and] super luminescent LEDs ... to emit [light] at about 1600 nm to about 1800 nm.” *Id.* at 13:16-25. In that example, emitter 104 includes both an LED configured to emit light at a first wavelength (“850 nm to 1350 nm”) and another LED configured to emit light at a second wavelength (“1600 nm to about 1800 nm”). Other examples are quoted below:

- “The emitter can include a plurality of *sets* of optical sources that, in an embodiment, are arranged together as a point source.” (JX-0001 at 9:4-6);
- “[T]he plurality of *sets* of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED.” (*id.* at 9:60-63);
- “[E]mitter 104 includes *sets* of optical sources that are capable of emitting visible and near-infrared optical radiation.” (*id.* at 12:10-12); and
- “[A]n emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302” and includes “emitter *sets* 1-*n* in the emitter 1304.” (*id.* at 33:22-36, FIG. 13).

Additionally, Figure 13 illustrates multiple “emitter *sets* 1-*n*”:



[REDACTED]

*Id.* at FIG. 13, 33:30-38; *see* CPHB at 125-126 (relying on same); CIB at 180 (relying on same). The specification explains that “emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302.” *Id.* at 33:22-25. By using “*sets 1-n*,” the figure and specification refer to multiple identical groups of LEDs.

The specification also refers to a singular “set” as having an LED of a first wavelength and another LED of a second wavelength. The specification discloses that “emitter 104 can include ... a *set* of top-emitting LEDs 1102 for emitting red and/or infrared light ...” JX-0001 at 29:19-22. To emit both red and infrared light, as taught by the specification, that set of LEDs has an LED emitting at a first wavelength and another LED emitting at a second wavelength. *Id.*

The specification’s use of the term “sets”—plural—discloses that the LEDs in each set are the same. Indeed, “sets” (plural) literally means groups of articles that resemble each other. Ex. 40 at 1035 (“A group of things of the same kind that belong together and are so used <a set of dishes>”); Ex. 41 at 1487 (“a group of similar things that belong together ... an extra set of keys”); Ex. 42 at 1475 (“a number of objects or people grouped or belonging together, often forming a unit or having certain features or characteristics in common.”).<sup>7</sup> A commonsense example is that, when one arranges four *sets* of silverware in preparing a dinner table, one would naturally understand that each set includes the same utensils (e.g., a fork, a knife, and a spoon). The individual utensils in each set correspond to a matching utensil in another set. In the same way, because the Poeze Patents’ specification repeatedly refers to the LEDs of each emitter 104 as “sets of LEDs,” any reader of the specification (and certainly a POSITA) would have understood that the LEDs in each set are the same.

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<sup>7</sup> Masimo requests that the Commission take judicial notice of these dictionary definitions.

[REDACTED]

Apple's positions before the Patent Office confirm that the Poeze Patents' specification discloses sets of LEDs with matching wavelengths in each set. Apple filed six IPR petitions challenging the validity of all three Poeze Patents. The Patent Office denied institution of *all six* petitions. And in the petitions challenging the '502 and '648 Patents, Apple and its expert explained their view of how a POSITA would have understood a "set of LEDs" and "sets of LEDs" in the Poeze Patents. Specifically, Apple argued that "[e]ach set of LEDs includes multiple LEDs, as was well known in the art, *with each set including LEDs with the same variety of wavelengths*, e.g., with the same three wavelengths, illustrated as red, yellow, and green circles." Ex. 44 at 19; Ex. 43 at 18-19 (same).<sup>8</sup> Apple further explained that "[a] POSITA would have expected success given that *the use of sets of LEDs of different wavelengths was well known in the art.*" Ex. 43 at 28; Ex. 44 at 28. Apple's explanation that such "sets of LEDs" were well known in the art leaves no question that the Poeze Patents satisfy the written description requirement for the claimed sets of LEDs. *See, e.g., Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005) (written description requirement must be applied in the context of the particular invention and the state of the art); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80 (Fed. Cir. 1986) (information well known in the art need not be described in detail in the specification).

The Poeze Patents' specification discloses that the emitters 104 contain sets of LEDs, and thus discloses that the LEDs have matching wavelengths in each set. By depicting two identical emitters 104, Figure 7B discloses that *each* emitter 104 has an identical set of LEDs—including

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<sup>8</sup> Masimo requests judicial notice of the IPR proceedings for the Poeze Patents (IPR Nos. IPR2022-01271 through IPR2022-01276) because the associated decisions were not issued until more than seven months after the evidentiary hearing. *See, e.g., Certain Infotainment Systems*, Inv. No. 337-TA-1119, EDIS Doc. ID 688912, Order No. 52 (Sept. 23, 2019). Apple also requested that the Commission take judicial notice of those IPR proceedings. RPR at 9 n.4.

[REDACTED]

the exemplary set with an LED at or about 1610 nm, an LED at about 1640 nm, and an LED at about 1665 nm. Therefore, the answer to question Q9a is yes.

2. **Q9b: Was Complainants' argument regarding 37 CFR 1.84(p)(4) raised in front of the ALJ, and if not, can the Commission still consider the argument?**

Masimo did not cite 37 C.F.R. § 1.84(p)(4) to the ALJ but did argue that the two emitters labeled 104 are identical, as explained below. Masimo raised this CFR rule in response to the ID's specific holding. The ID held that the Poeze Patents' "disclosures would not convey to persons of ordinary skill in the art that sets of LEDs with matching wavelengths were part of the alleged invention—there is no suggestion that two LEDs emit the same wavelengths ...." ID at 164. This holding suggested to Masimo that the ID overlooked Masimo's argument about Figure 7B and emitters 104 being identical, and the extensive discussion in the specification that makes the support for the claims clear.

In its Pre-Hearing Brief, Masimo argued that "[a] POSITA would have underst[oo]d from the disclosure of emitter 'sets' that *corresponding LEDs in each set have the same wavelength* to allow the sensor to collect data from multiple measurement sites with multiple light paths." CPHB at 126. In its Post-Hearing Brief, Masimo reproduced Figure 7B and specifically argued that its emitters 104 provide "support for sets of LEDs each emitting at a first wavelength and a second wavelength." CIB at 179-180. Masimo quoted the specification's description that "[i]n an embodiment, the emitter 104 includes *sets of optical sources* that are capable of *emitting visible and near-infrared optical radiation*." CIB at 180 (emphasis in original) (quoting JX-0001 at 12:9-12). Because the ID did not address Figure 7B and its emitters 104, Masimo's Petition for Review reinforced Masimo's argument that emitters 104 in Figure 7B must be the same because they both are designated with the same numeral. In making this same-numeral argument, Masimo cited 37 C.F.R. § 1.84(p)(4) as support. CPR at 36-40.

# EXHIBIT 43

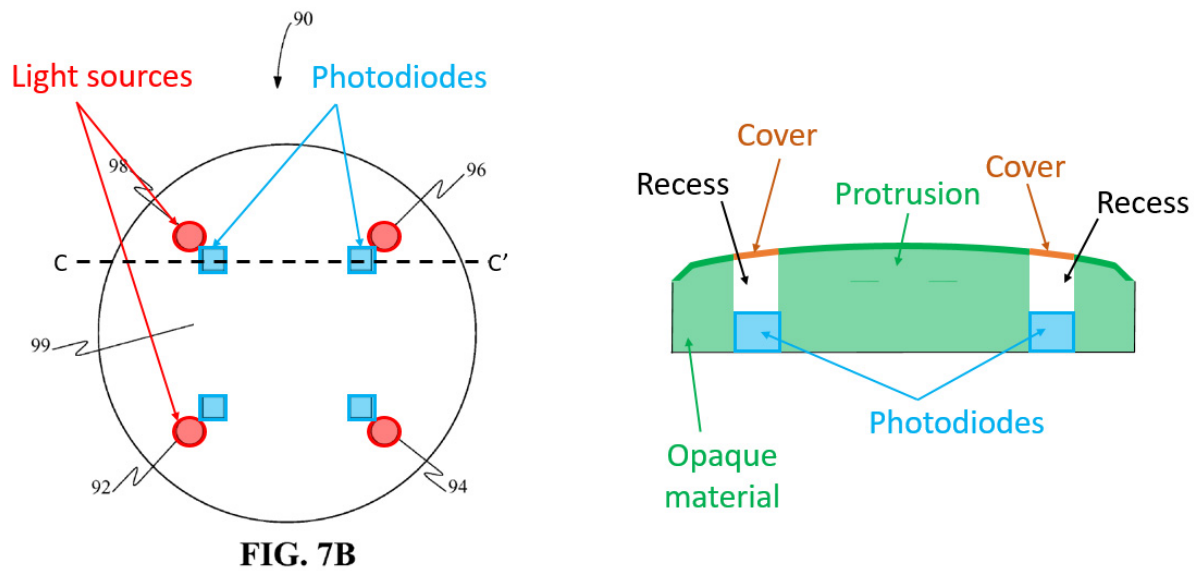
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent of: Poeze et al.  
U.S. Patent No.: 10,912,502 Attorney Docket No. 50095-0043IP2  
Issue Date: February 9, 2021  
Appl. Serial No.: 17/031,407  
Filing Date: September 24, 2020  
Title: USER-WORN DEVICE FOR NONINVASIVELY MEASURING  
A PHYSIOLOGICAL PARAMETER OF A USER

**Mail Stop Patent Board**

Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT  
NO. 10,912,502 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42**



Left: Composite figure based on Lumidigm, Fig. 7B; Right: Composite figure based on C-C' cross-section

As shown above, in each alternative arrangement, each photodiode (blue) is separately recessed into the protrusion (green), and a cover (orange) extends over each recess. *See* APPLE-1006, 7:5-10, 8:1-10; APPLE-1025, 9:1-15; APPLE-1003, ¶71.

Optionally, in the combination, each of the light sources is a “set[] of LEDs,” as taught by Lumidigm, illustrated for two representative light sources in each of the Fig. 7A and modified Fig. 6 arrangements *infra*. APPLE-1006, 6:43-53; *see* 9:12-34. Each of these sets of LEDs in the combination includes multiple LEDs, as was well known in the art. Moreover, each multiple-LED set includes LEDs with the same variety of wavelengths, *e.g.*, with the same three wavelengths, as illustrated by the red, yellow, and green circles in each set of LEDs in the

figures *infra*. See APPLE-1006, 6:43-48; APPLE-1015, Fig. 9, 7:64-66; APPLE-1023, Fig. 7, 9:22-29; APPLE-1013, 86-87; APPLE-1003, ¶¶72-73.

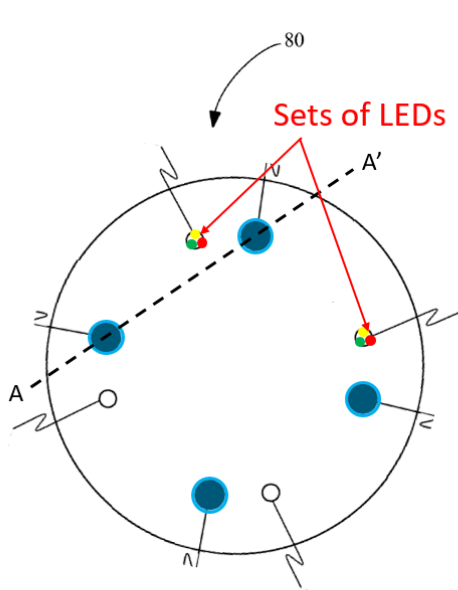


FIG. 6

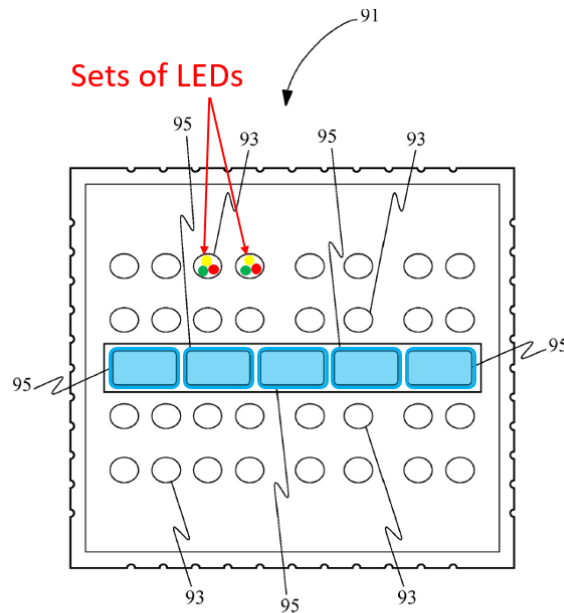


FIG. 7A

Composite figures based on Lumidigm, modified Fig. 6 (left) and Fig. 7A (right)

### 5. Reasons to combine Lumidigm, Scharf, and Kotanagi

A POSITA would have been motivated to implement the Lumidigm-Scharf-Kotanagi combination for at least the following reasons. APPLE-1003, ¶¶74-111.

A POSITA would have been motivated to arrange the LEDs and detectors according to the arrangement in Lumidigm's Fig. 7A

A POSITA would have been motivated to pursue modifying the sensor of Lumidigm's Fig. 2 such that the LEDs and detector are arranged according to the arrangement of Lumidigm's Fig. 7A for at least the following reasons. APPLE-1003, ¶¶75-79.



# EXHIBIT 44

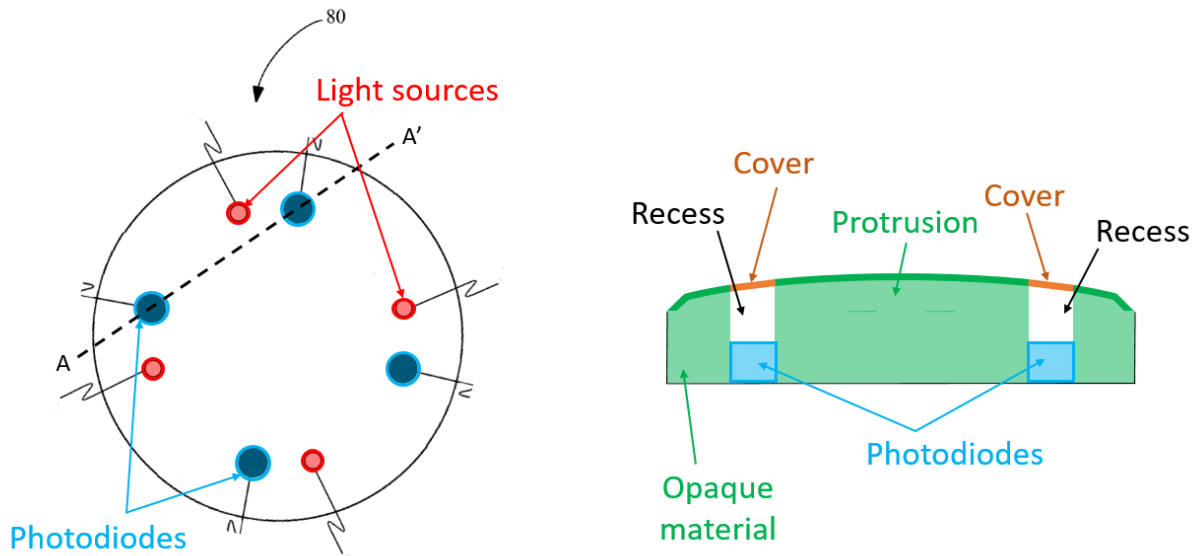
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent of: Poeze et al.  
U.S. Patent No.: 10,945,648 Attorney Docket No. 50095-0044IP2  
Issue Date: March 16, 2021  
Appl. Serial No.: 17/031,316  
Filing Date: September 24, 2020  
Title: USER-WORN DEVICE FOR NONINVASIVELY MEASURING  
A PHYSIOLOGICAL PARAMETER OF A USER

**Mail Stop Patent Board**

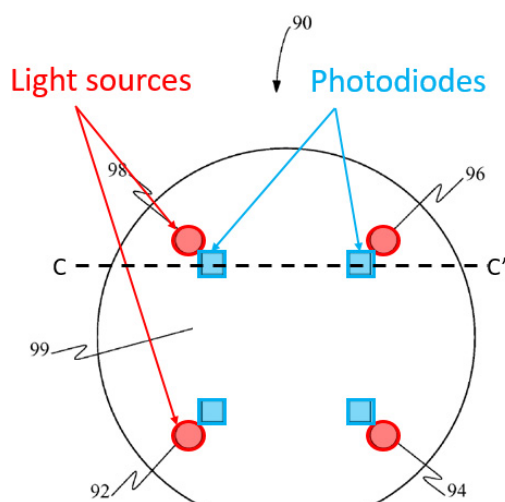
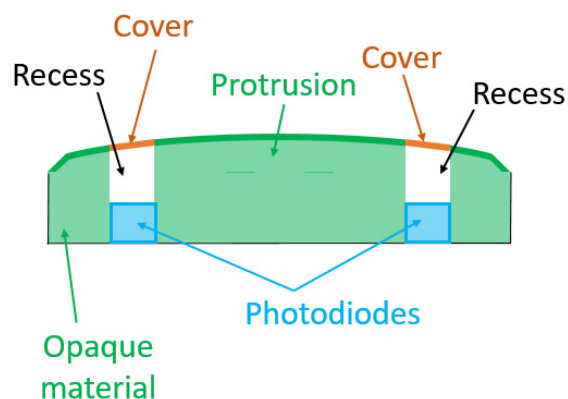
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT  
NO. 10,945,648 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42**

**FIG. 6**

Left: Composite figure based on Lumidigm, Fig. 6 (annotated); Right: Composite figure based on A-A' cross-section (not to scale)

With respect to Fig. 7B, Lumidigm describes that a sensor includes “multiple light sources ... placed at the perimeter of a detector array.” APPLE-1006, 9:34-39. In the combination, this arrangement is modified to include fewer than all of the photodiodes in the array, as shown *infra*. APPLE-1003, ¶67; see APPLE-1006, 9:42-45.

**FIG. 7B**

Left: Composite figure based on Lumidigm, Fig. 7B; Right: Composite figure based on C-C' cross-section (not to scale)

In each alternative arrangement, each photodiode (blue) is separately recessed into the protrusion (green), and a cover (orange) extends over each recess. See APPLE-1006, 7:5-10, 8:1-10; APPLE-1025, 9:1-15; APPLE-1003, ¶¶68.

Optionally, each of the light sources is a “set[] of LEDs,” as taught by Lumidigm, illustrated for two representative light sources in the Fig. 7A and modified Fig. 6 arrangements *infra*. APPLE-1006, 6:43-53; see 9:12-34. Each set of LEDs includes multiple LEDs, as was well known in the art, with each set including LEDs with the same variety of wavelengths, *e.g.*, with the same three wavelengths, illustrated as red, yellow, and green circles. See APPLE-1006, 6:43-48; APPLE-1015, Fig. 9, 7:64-66; APPLE-1023, Fig. 7, 9:22-29; APPLE-1013, 86-87; APPLE-1003, ¶¶69-70.

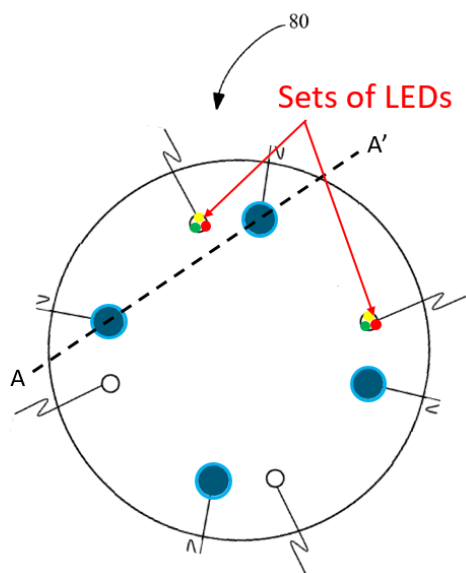


FIG. 6

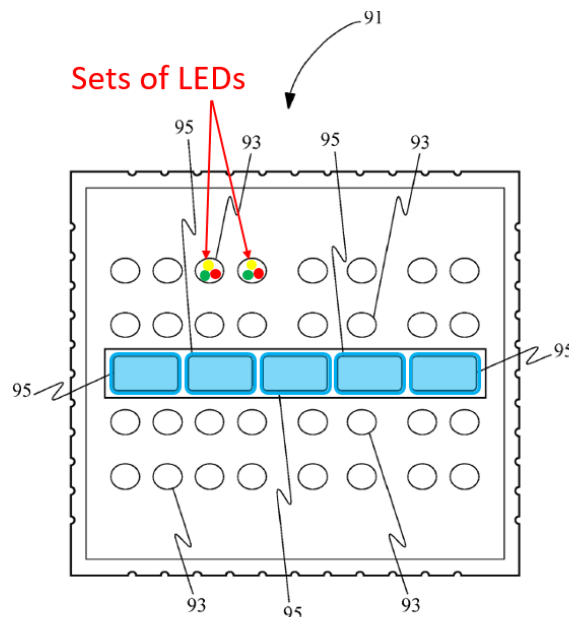


FIG. 7A

Composite figures based on Lumidigm, modified Fig. 6 (left); Fig. 7A (right)

### 5. Reasons to combine Lumidigm, Scharf, and Kotanagi

A POSITA would have been motivated to implement the Lumidigm-Scharf-Kotanagi combination described in the preceding section for at least the following reasons. APPLE-1003, ¶¶71-108.

A POSITA would have been motivated to arrange the LEDs and detectors according to the arrangement in Lumidigm's Fig. 7A

A POSITA would have been motivated to arrange the LEDs and detectors according to the arrangement of Lumidigm's Fig. 7A as follows. APPLE-1003, ¶¶72-76.

First, a POSITA would have been motivated to pursue this implementation to achieve the advantages of the arrangements of Fig. 7A, which "provide[s]

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of  
CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**RESPONDENT APPLE INC.'S RESPONSE TO THE COMMISSION'S NOTICE TO  
REVIEW IN PART A FINAL INITIAL DETERMINATION AND REQUEST FOR  
WRITTEN SUBMISSIONS**

[REDACTED]

Masimo has still not “put[] W1 into the consumer channel, because we didn’t want the consumers to think that [the W1] is the watch we have in mind.” Masimo now says it is instead focused on a different product, the “Freedom” watch, which has to this day yet to be released. According to Masimo’s CEO, Masimo “want[s] [consumers] to first know Masimo as Freedom that is a much more beautiful design and has a lot more features,” as compared to the W1. Masimo May 9, 2023 Q1 2023 earnings call.<sup>6</sup>

- Although Complainants claimed more than [REDACTED] in expenditures as allegedly attributable to “Masimo Watch” prototypes at the hearing, that claim unraveled when they presented their case. The ALJ disregarded over [REDACTED] of the claimed expenditures based on a lack of reliable evidence to support them.
- The only documentary evidence supporting the remaining [REDACTED] in alleged expenditures are three made-for-litigation spreadsheets containing facially implausible allocation percentages provided by financially-interested executives and unsupported by even a shred of contemporaneous documentation.

Given the nascent state of Complainants’ “Masimo Watch” product development at the time of the complaint, it is no surprise that their economic prong evidence was so flimsy. This threadbare record is not remotely enough to justify an import ban on the accused Apple Watch products. For the Commission to enter an exclusion order, it would need to contravene Section 337 and prior precedent in at least four ways. **First**, the Commission would need to find, contrary to the Federal Circuit’s decision in *Microsoft Corp. v. ITC*, that a complainant can

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<sup>6</sup> A transcript of the call is *available at*: <https://seekingalpha.com/article/4602257-masimo-corporation-masi-q1-2023-earnings-call-transcript>.

[REDACTED]

satisfy the domestic industry requirement without a patent-practicing article at the time the complaint was filed. **Second**, in the absence of a patent-practicing article existing as of the complaint, the Commission would need to rely on post-complaint evidence—and do so in the admitted absence of any “significant and unusual circumstances” warranting such reliance. **Third**, the Commission would need to find, contrary to prior investigations, that a complainant can satisfy the economic prong based on *ipse dixit*, conclusory time allocations, including expenditures attributed to labor by executives and by recruiters without a demonstrated relationship to the domestic product, unsupported by any contemporaneous documentation. **Fourth**, the Commission would effectively need to endorse the legal premise that a “domestic industry” can be comprised of hopes, aspirations, and extremely early technical development—thereby opening the door to ban the import of real products to “protect” a vision that might never come to fruition. Simply put, that is not the law.

**1. Question 1: What evidence and argument was presented to the ALJ that shows that Complainants were developing, as of the filing of the Complaint, the Masimo Watch and that the Masimo Watch would practice the Poeze and '745 patent claims?**

As this question correctly recognizes, “only activities that occurred before the filing of a complaint with the Commission are relevant to whether a domestic industry exists or is in the process of being established.” *Certain Coaxial Cable Connectors, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-650, Comm’n Op. at 51 n.17 (Apr. 14, 2010). Under *Microsoft Corp. v. ITC*, 731 F.3d 1354, 1362 (Fed. Cir. 2013), the relevant inquiry is whether Complainants had at the time of the Complaint an **actual article** that practiced the patents. They did not. And what Complainants alleged in their Complaint to be the actual article did not exist at the time the Complaint was filed. While Apple submits that it is irrelevant whether Complainants had evidence or argument that they were in the process of **developing** a



[REDACTED]

product that *would* practice the patents, Complainants’ evidence does not show that, either.

a) **Complainants Had No Patent-Practicing Article At The Time Of The Complaint.**

Complainants initiated this Investigation by claiming that “*the* Masimo Watch is protected by one or more of claims of each of the ’501 Patent, the ’502 Patent, the ’648 Patent, and the ’745 Patent,” and that “a confidential sample of a Masimo Watch that embodies the claims [of the Poeze and ’745 patents] is available upon request.” Complaint ¶¶ 47, 54, 61, 68, 86. In support of their claims, Complainants attached to the Complaint purported CAD images of the alleged Masimo Watch within attached claim charts. *See id.*, Ex. 22. But it is undisputed that no [REDACTED] [REDACTED] Tr. [Scruggs] 454:3-455:13; RX-1209C [Scruggs Dep.] 173:11-174:18. Absent such a device, Complainants instead identified throughout discovery scores of different items as their alleged domestic industry articles. RX-1183C.0010-26, 44-86. Ultimately, Complainants settled on eight different items—alleged to practice different claims of the four asserted patents—as their asserted DI articles. ID at 5.

But Complainants failed to demonstrate that as of the time of the Complaint any of these items practiced a claim of the Poeze or ’745 patents.

To start, only one of the asserted DI articles—CPX-0052C, the “Rev A” sensor—[REDACTED] [REDACTED] *See* RPFR at 28-29. Each of the other alleged DI articles was [REDACTED]:

- CPX-0020C was [REDACTED] [REDACTED] Tr. [Scruggs] 458:1-17.
- CPX-0146C (the so-called “W1”) was [REDACTED] [REDACTED] *Id.* 398:24-399:9; *see also* ID at 59, 84.

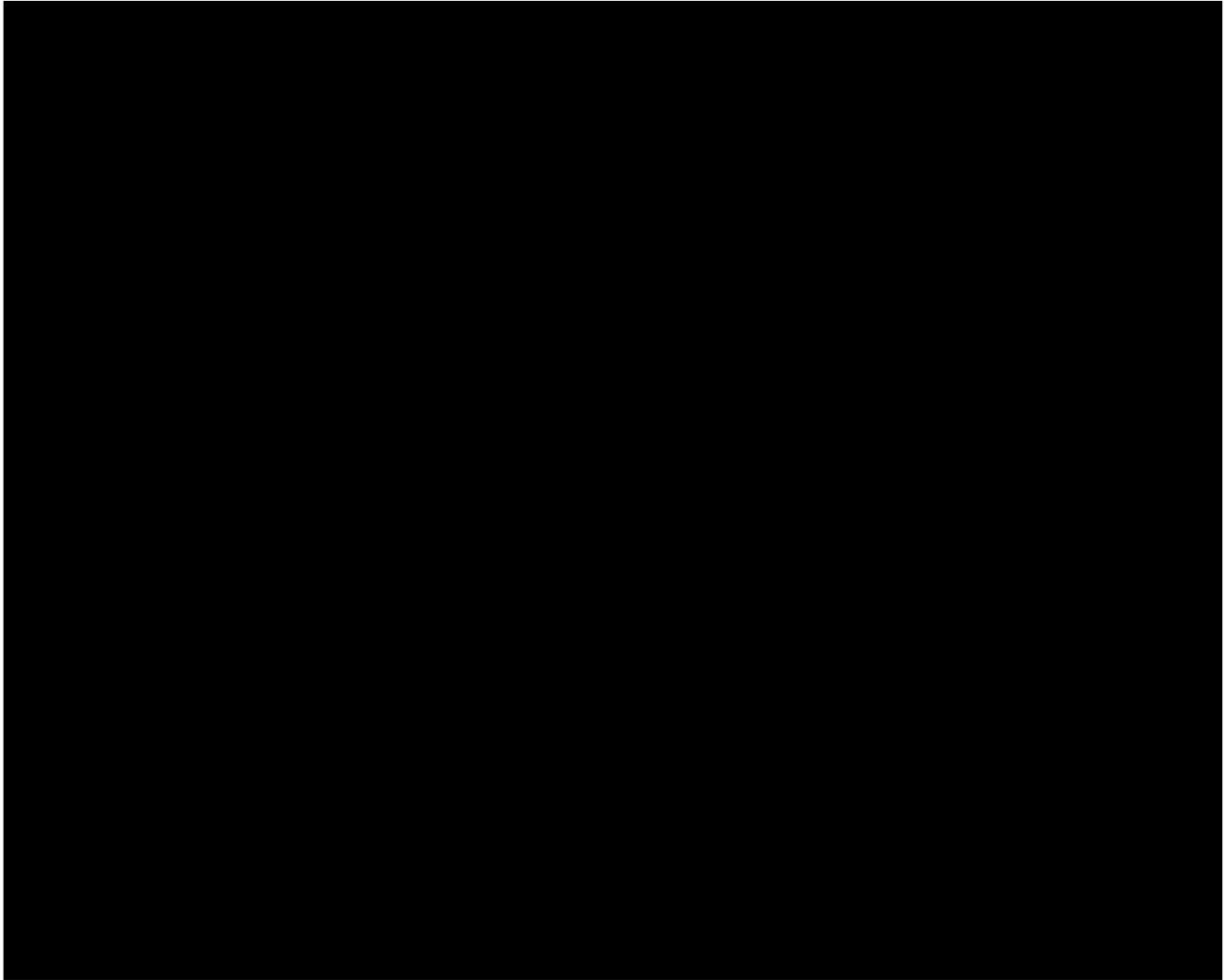
- [REDACTED]
- CPX-0058C [REDACTED]  
[REDACTED] — [REDACTED] Tr. [Scruggs]  
459:4-460:12; Tr. [Sarrafzadeh] 1121:9-24; RX-1183C.0035.
  - Complainants failed to prove that CPX-0019C and CPX-0065C [REDACTED]  
[REDACTED]  
[REDACTED] Tr. [Scruggs]  
398:20-23. Each of these devices was also [REDACTED]  
[REDACTED] ID at 84 n.23; RX-1183C.0037-0039. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]. *See also* CRPFR at 29 n.5.
  - CPX-0021C [REDACTED]. Tr. [Scruggs] 461:17-25.
  - And the ALJ correctly found that there was no evidence that either CPX-0021C or CPX-

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<sup>7</sup> Complainants’ Amended Complaint should be accorded a filing date of July 7, 2021, the date on which they successfully filed confidential and public versions of the Amended Complaint, not the July 12, 2021 date, which has unjustly benefited Complainants. As Complainants admit, they “attempted to file both public and confidential versions of their Complaint *on July 7, 2021.*” CRPFR at 29. Further, as Complainants have now documented by submitting the “EDIS Notice of Acceptance of Electronic Documents” they received on July 7 for both versions, they successfully filed the confidential and public versions of the Complaint on that date. *Id.* at Appendix H (“EDIS Notice of Acceptance” for public version, DocID 746186); *id.* at Appendix J (“EDIS Notice of Acceptance” for confidential version, DocID 746189). Apparently, some inadvertence or error—possibly confusion between DocID 746186 and DocID 746189—resulted in a request that Complainants refile the confidential version on July 12 (DocID 746514). The document filing data on EDIS for what is now showing as the public version at DocID 746186 indicates that the original filing was made on July 7, but the document that is now on the system has a “Create Date” of July 20, 2023 (after Apple’s counsel notified Complainants’ counsel, and the Secretary’s office notified users, that the “public” complaint contained a Confidential designation). *See id.* at Appendix M; Appendix L. Complainants were also notified by the Commission on July 20 that “straightening out the document’s status should not have any effect on the timing of the Commission’s decision on institution.” *Id.* at Appendix N. Whether the filing error was attributable to Complainants or to processing of the filings, Complainants should not be permitted to reap the benefits of the mere chance that required them to refile their Complaint on July 12 to suggest that they had established a domestic industry prior to their Complaint by now relying on devices or other evidence post-dating July 7, 2021.

0029C [REDACTED]—as required to  
practice claim 18 of the ’745 patent—as of the Complaint. ID at 205, 207-209.

As shown below, CPX-0052C is a far cry from the “Masimo Watch” depicted in the  
Complaint:



Moreover, as discussed in Apple’s Petition for Review, Complainants failed to show that  
CPX-0052C (or the other alleged DI articles) practices any claim of the Poeze Patents or the ’745  
patent. *First*, it is indisputable that CPX-0052C as relied on (and shown above) is not a “user-  
worn” device as required by the Poeze Patents. CPX-0052C [REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED] RIB at 45-46; RPFR at 35-36.

*Second*, Complainants failed to prove that CPX-0052C (or the other asserted DI articles) could “measure,” “calculate,” or “determine” measurements of a physiological parameter (such as blood oxygen saturation) as required by all asserted DI claims of the Poeze and ’745 patents. RPFR at 29-35, 72-73. Complainants failed to introduce *any* source code (much less code existing at the time of the Complaint) showing that CPX-0052C (or any alleged DI device) was configured to calculate a physiological parameter; nor did Complainants demonstrate this purported functionality of CPX-0052C (or any of the other prototypes) at the hearing. RIB at 46-52, 176-177; RPFR at 29-35, 72-73. The only record evidence of the functionality (or lack thereof) of CPX-0052C are results of demonstrations attended and recorded by *Apple’s experts*, both of whom testified that those demonstrations did *not* show that CPX-0052C was measuring a physiological parameter. To the contrary, as Apple’s experts testified, Complainants refused to allow them to compare CPX-0052C against any reference device (such as one of Masimo’s commercially-available pulse oximeters) to confirm it was in fact taking a physiological measurement, and the readings reported by the device were too erratic to conclude it was in fact doing so. Tr. [Sarrafzadeh] 1122:16-1124:23; Tr. [Warren] 1254:4-1256:1; *see also* RIB at 46-52, 176-177; RPFR at 29-35, 72-73. For example, CPX-0052C reported pulse rates ranging from

[REDACTED]  
[REDACTED]  
[REDACTED] Tr. [Sarrafzadeh] 1122:3-1124:3; *id.* [Warren] 1254:4-1256:1; *id.* [Scruggs] 419:8-14, 445:2-16, 446:3-7, 447:24-452:14; RX-1470C; RIB at 46-52; RPFR at 29-35. And the purported blood oxygen saturation readings from CPX-0052C were similarly suspect, with the device *only* reporting [REDACTED] — [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. [Scruggs] 449:13-450:1; *see also* RX-1470C.

Acknowledging the deficiencies in Complainants' evidence, the ALJ relied substantially on "circumstantial" evidence of testing of prototypes *other than* CPX-0052C itself to find the technical prong satisfied. *See, e.g.*, ID at 62 n.16-17. For example, [REDACTED]

[REDACTED]

[REDACTED] ID at 60<sup>8</sup>; *see also* RPFR at 30-31. But testing of a purportedly "similar" device is not probative of the capabilities of CPX-0052C, particularly where (1) CPX-0052C itself was available and Complainants declined to proffer any proof of its operation and (2) there is evidence confirming that not all RevA devices are created equally in terms of functionality and performance. *See* RPFR at 31 n.17. Accordingly, Complainants have failed to show that any alleged DI article existed at the time of the Complaint and practiced the Poeze and '745 patents.

b) **Complainants Did Not Introduce Evidence Sufficient To Show That, As Of The Time Of The Complaint, "The Masimo Watch" Practiced Or Would Practice The Poeze And '745 Patents.**

Because Complainants have failed to meet their burden to show the existence of an actual article practicing the Poeze and/or '745 patents as of the filing of the Complaint, they cannot satisfy the technical prong. Although Apple maintains it is irrelevant, to the extent the Commission also considers whether Complainants had—as of the time of the Complaint—evidence that they were developing a "Masimo Watch" that *would* practice those patents at some future point in time, no such evidence or argument was presented.

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<sup>8</sup> Emphases added throughout unless otherwise noted.

[REDACTED]  
[REDACTED]  
Complainants introduced no [REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] Tr. [McGavock] 544:2-3. As discussed above, Complainants submitted with their Complaint CAD images purportedly depicting a “Masimo Watch” that mapped to claims of the Poeze and/or ’745 patent. But these images of a [REDACTED]

[REDACTED] and presumably for that purpose. RX-1209C [Scruggs Dep.] 34:19-35:18 [REDACTED]

[REDACTED] *Id.* 173:11-175:11 (Mr. Scruggs testifying [REDACTED]  
[REDACTED] [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] *E.g., id.* 92:2-93:7, 107:2-24; Tr. [Scruggs] 466:5-10, 467:8-18. Moreover, a CAD image is not an “article,” and CAD drawings alone cannot serve as evidence of a device that would have practiced the patents at issue. *See Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing the Same*, Inv. No. 337-TA-1073, Comm’n Op. at 12 (Aug. 12, 2019). As discussed above, each asserted DI claim requires “calculating,” “determining,” or “measuring” a physiological parameter. Complainants introduced nothing existing as of the time of the Complaint—such as source code—sufficient to show Complainants could and would make a “Masimo Watch” capable of satisfying those claim limitations.

[REDACTED]

The ID relied on only two pre-Complaint documents—CX0364C and CX-0783C—as allegedly evincing that “prototypes ...designed and built [REDACTED] ... were part of the ongoing project to design and manufacture the Masimo Watch.” ID at 321. But neither document supports this conclusion or shows Masimo’s intention to create a device that would practice the Poeze and/or ’745 patents. CX-0364C, entitled [REDACTED]

[REDACTED]

[REDACTED] CX-0364C at 19. The document [REDACTED]

[REDACTED]

[REDACTED] CX-0783C, a 15-  
page [REDACTED]

[REDACTED]

[REDACTED] Nothing in the record suggests any of those is the “Masimo Watch” that was the basis for Complainants’ claimed domestic industry. To the contrary, there are obvious distinctions between the envisioned “Freedom” products described therein and the “Masimo Watch” as presented in this Investigation. For example, CX-0783C lists [REDACTED]

[REDACTED].

CX-0783C at 2, 8; Tr. [Muhsin] 385:11-25; *id.* [Scruggs] 468:18-469:2. And like CX-0364C, CX-0783C [REDACTED]

[REDACTED]. In short, Complainants failed to introduce any evidence showing that “the Masimo Watch” was in development as of the time of the Complaint

[REDACTED]

and would practice the Poeze and '745 patents.

**2. Question 2: Should the Commission consider evidence post-dating the Complaint, such as the final design of the Masimo Watch, to establish that Complainants were developing a physical article that would practice the Poeze patents and the '745 patent?**

The Commission should not consider evidence post-dating the Complaint and instead should affirm the ALJ's determination to disregard such evidence, including the design of the Masimo W1. The ALJ properly applied the Commission's longstanding precedent, affirmed by the Federal Circuit, that satisfaction of the domestic industry requirement should be determined as of the complaint filing date, and the corollary that evidence regarding post-complaint activities should be disregarded. ID 56-59.

The Commission has long held—and Complainants do *not* dispute (CPFR at 46-54)—that, with limited exceptions, satisfaction of the domestic industry requirement is to be evaluated as of complaint filing. *Certain Coaxial Cable Connectors, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-650, Comm'n Op. at 51 n.17 (Apr. 14, 2010) (“We note that ***only activities that occurred before the filing of a complaint*** with the Commission are relevant to whether a domestic industry exists or is in the process of being established under sections 337(a)(2)-(3).”); *see also Certain Video Game Systems & Controllers*, Inv. No. 337-TA-743, Comm'n Op. at 5 (Jan. 20, 2012), *aff'd sub nom. Motiva, LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013) (same); *Bally/Midway Mfg. v. U.S. Int'l Trade Comm'n*, 714 F.2d 1117, 1120 (Fed. Cir. 1983). The Commission has rejected the use of post-complaint evidence that would thereby “treat the domestic industry analysis as a moving target.” *Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing the Same*, Inv. No. 337-TA-1073, Comm'n Op. at 8 n.11 (Aug. 12, 2019). Masimo's design of the Masimo W1, which Complainants acknowledge [REDACTED]



that, in the context of Figure 7B or the relevant claims, the inventors possessed the claimed sensor including two separate *sets* of LEDs, each with LEDs emitting in at least two *matching* wavelengths, for measurement of oxygen or oxygen saturation.

In short, Complainants’ attempt to mix and match different features from different embodiments—*none* of which describes two matching sets of LEDs for measuring blood oxygen—fails to establish written description support for the specifically claimed combination of elements as a whole. As the Federal Circuit has repeatedly confirmed, “[t]he written description requirement is not met when, as here, the specification provides at best disparate disclosures that an artisan might have been able to combine in order to make the claimed invention.” *Flash-Control, LLC v. Intel Corp.*, No. 2020-2141, 2021 WL 2944592, at \*4 (Fed. Cir. July 14, 2021) (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010)); *Ariad*, 598 F.3d at 1352 (“[I]t is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.” (citations omitted)).

**b) Was Complainants’ argument regarding 37 CFR 1.84(p)(4) raised in front of the ALJ, and if not, can the Commission still consider the argument?**

This argument was *not* raised in front of the ALJ and should not be considered by the Commission. Complainants contend that the ID “was clearly erroneous and based on legal error” because it failed to “adhere to Patent Office rules that the two emitter sets 104 are presumed to be identical.” *Id.* at 39. But Complainants *never* made before the ALJ the argument on which they focus their Petition—namely, that the specification includes as one of many examples of “emitter 104” an emitter that can emit “at or about 1610 nm, about 1640nm, and about 1665 nm” or at eight different wavelengths (JX-001 [‘501 patent] at 12:35-40, 12:64-13.1);

[REDACTED]

that Figure 7B’s reference to “emitters 104” would necessarily include this example to the exclusion of the myriad of other examples; and that both “Emitters 104” in Figure 7B must be presumed to be identical. *Compare id.* at 33-40 with CPHB at 125-126, CIB at 179-180, and CRB at 103.<sup>16</sup>

Complainants’ new argument is untimely and waived, as it was advanced in *none* of Complainants’ pre- or post-hearing briefs. Order No. 4 [Ground Rules] 9.2, 13.1, 13.2; *In re Baxter Int’l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012). The Commission should accordingly disregard it as such. *See Certain Prod. Having Laminated Packaging, Laminated Packaging, & Components Thereof*, Comm’n Op. at 9, Inv. No. 337-TA-874 (Sept. 3, 2013) (“On petition for review, [Complainant] attempts to recast the evidence of record to segregate box-related expenses. Insofar as these arguments were not presented to the ALJ in [Complainant]’s post-hearing brief, they have been waived.” (citing ALJ ground rules)); *see also Certain Digital Video Receivers & Related Hardware & Software Components*, Inv. No. 337-TA-1103, Comm’n Op. at 41 (May 13, 20202) (“The Commission agrees with Comcast that Rovi has waived direct infringement by Comcast by failing to allege such infringement in Rovi’s post-hearing brief.”).

c) **Is 37 CFR 1.84(p)(4) binding authority on the Commission and does it require the Commission to presume that each emitter set 104 is identical?**

Even if the Commission were to consider Complainants’ new argument (which it should not), 37 CFR § 1.84(p)(4) does not require the Commission to presume that each “emitter 104” is

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<sup>16</sup> Complainants’ only effort in their pre- and post-hearing briefs to address the requirement of matching wavelengths was a reference to the specification’s statement that emitter 104 could include “sets of optical sources that are capable of emitting visible and near-infrared optical radiation.” JX-001 [’501 patent] at 12:9-12. As referenced above, however, “visible and near-infrared optical radiation” are *not* specific wavelengths. Instead, each encompasses a large spectrum of *different* wavelengths. *Id.* at 13:5-8.

identical. This regulation—which is directed to patent applicants when preparing drawings—provides:

The same part of an invention appearing in more than one view of the drawing must always be designated by the same reference character, and the same reference character must never be used to designate different parts.

As the text confirms, this regulation provides guidance during Patent Office proceedings that the “same part” of the invention (*e.g.*, an emitter) should be designated by the same reference character (*i.e.*, identifying numeral). In this instance, however, although “emitter 104” is used in various embodiments, the specification makes clear that the structure of this component can vary widely, that the inventors intended this reference number to encompass a wide assortment of different types of emitters, and that there is no reason that “emitters 104” should be treated identically, even when used in the same embodiment.

The ITC has considered § 1.84(p)(4) in only a few cases. In *Certain Movable Barrier Operator Systems*, the ALJ cited MPEP§ 608.02 (which in turn cited 37 CFR § 1.84(p)(4)) in finding that two different data “packets” in a prior art patent drawing, with different labels, would have been understood not to be identical and, on that basis, concluded that the reference did not disclose “multiple copies of a message being transmitted.” Inv. No. 337-TA-1209, Final Initial Determination, 2021 WL 4843816, at \*68 (Sept. 14, 2021). The Commission **reversed** the ALJ’s finding regarding “multiple copies,” without commenting on the application of § 1.84(p)(4). Inv. No. 337-TA-1209, Comm’n Op., 2022 WL 795701, at \*20-21 (Mar. 11, 2022). In *Certain Devices for Improving Uniformity Used in a Blacklight Module*, the Commission cited 37 CFR § 1.84(p)(4) in finding (in the context of an anticipation analysis) that, because one embodiment met a limitation based on including a particular feature, a different embodiment also met the limitation because it included the same feature labeled with same reference number. Inv. No. 337-TA-805, Comm’n Op., 2013 WL 12447250, at \*15 (May 17,

**B. Questions Regarding The Public Interest**

- 1. Question 1: Please identify any ongoing or formally planned studies that use the blood oxygen features of the Apple Watches. Should the Commission allow an exemption or delay the effective date of any remedial relief so as to permit importation of the infringing Apple Watches for purposes of conducting such studies? Please explain the rationale and the scope of any such exemption or delay.**

To exclude Apple Watch from the United States would deprive researchers of an important tool for conducting research into health and wellness issues related to blood oxygen—and other physiological measurements taken by the Accused Apple Watches—and the Commission should ensure that its own actions do not impede such research. For example, the ongoing Apple Heart and Movement Study—sponsored by Apple in conjunction with Brigham and Women’s Hospital and the American Heart Association—uses blood oxygen measurements (together with other health and wellness metrics available through Apple Watch) as part of a “broad study of factors that affect heart health and potentially cause deterioration in mobility or overall well-being, in an effort to promote healthy movement and improved cardiovascular health.”<sup>17</sup> Similarly, the Apple Women’s Health Study—conducted in collaboration with Harvard T.H. Chan School of Public Health and the NIH’s National Institute of Environmental Health Sciences (NIEHS)—collects blood oxygen data and other measurements “to advance the understanding of menstrual cycles and their relationship to various health conditions, including

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<sup>17</sup> ClinicalTrials.gov, “Apple Heart & Movement Study,” <https://clinicaltrials.gov/ct2/show/NCT04198194?term=apple+heart+and+movement+study&draw=2&rank=1>; Apple, Press Release, “Apple Launches Three Innovative Studies Today in the New Research App” (Nov. 14, 2019), <https://www.apple.com/newsroom/2019/11/apple-launches-three-innovative-studies-today-in-the-new-research-app/>; *see also* American Heart Association, Apple Heart and Movement Study, <https://www.heart.org/en/get-involved/apple-heart-and-movement-study>.

polycystic ovary syndrome (PCOS), infertility, osteoporosis and menopausal transition.”<sup>18</sup> A key benefit of Apple Watch for such studies is that researchers can use the multiple health and wellness metrics available through the Accused Apple Watches (as opposed to a single data field), helping to advance scientific discovery by identifying how various metrics relate to certain conditions.

Beyond the studies sponsored by Apple, researchers in the United States have conducted and are conducting other studies involving the Blood Oxygen feature,<sup>19</sup> including research by Anthem (now Elevance Health) and the University of California, Irvine to assess whether using Apple Watch can help individuals with asthma manage their condition and predict potential asthma exacerbations<sup>20</sup>; research at the Mayo Clinic using Apple Watch to monitor patients during

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<sup>18</sup> ClinicalTrials.gov, “Apple Women’s Health Study,” <https://clinicaltrials.gov/ct2/show/NCT04196595?term=apple+women%27s+health+study&draw=2&rank=1>; Apple, Press Release, “Apple Launches Three Innovative Studies Today in the New Research App” (Nov. 14, 2019), <https://www.apple.com/newsroom/2019/11/apple-launches-three-innovative-studies-today-in-the-new-research-app/>; *see also* Harvard T.H. Chan School, “Collaborating for Discovery in Women’s Health,” <https://www.hsph.harvard.edu/applewomenshealthstudy/>.

<sup>19</sup> Apple, Press Release, “With Apple Watch, researchers explore new frontiers in heart health” (Feb. 21, 2023), <https://www.apple.com/newsroom/2023/02/with-apple-watch-researchers-explore-new-frontiers-in-heart-health/> (Texas A&M University and Stanford University equipping firefighters with Apple Watch to study the impact of wildfire smoke on heart health, including blood oxygen saturation).

<sup>20</sup> “Anthem, UCI Will Investigate How Digital Tools Can Aid Asthma Management,” Univ. Cal. Irvine (Sept. 16, 2020), <https://news.uci.edu/2020/09/16/anthem-uci-will-investigate-how-digital-tools-can-aid-asthma-management/> (“The digital asthma tool includes daily symptom and trigger tracking to provide awareness of asthma control and personalized nudges based on changes in signals from their Apple Watch including activity, heart rate, the new Blood Oxygen feature and other health metrics.”); *see also* ClinicalTrials.gov, “Asthma Digital Study (ADS)” (last update posted Jan. 3, 2022), <https://clinicaltrials.gov/ct2/show/NCT04609644>.

endoscopic procedures<sup>21</sup>; and research at Indiana University comparing Apple Watch to other available pulse oximetry technologies on the market.<sup>22</sup>

One area of research in which the Accused Apple Watches could potentially be impactful relates to racial disparities in healthcare and the role that pulse oximetry plays in those disparities. For example, a recent study published in the *Journal of the American Medical Association (JAMA)* found that “racial and ethnic biases in pulse oximetry accuracy were associated with greater occult hypoxemia in Asian, Black, and non-Black Hispanic patients with COVID-19, which was associated with significantly delayed or unrecognized eligibility for COVID-19 therapies among Black and Hispanic patients.”<sup>23</sup> During the development of the Blood Oxygen feature, Apple dedicated significant resources to ensuring that Apple Watch worked well for people of all skin tones. Apple’s own research, including a desaturation study published in 2022 conducted on fifty healthy adult subjects, showed no “skin-tone dependence” for blood oxygen measurements taken by Apple Watch when compared with contemporaneous blood tests.<sup>24</sup> Apple Watch could therefore be an important research tool and reference point for those seeking to study and correct this disparity. As another example, researchers at Morehouse

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<sup>21</sup> ClinicalTrials.gov, “Wearable Technology in Endoscopy” (last update posted Apr. 18, 2023), <https://clinicaltrials.gov/ct2/show/NCT05044104> (Mayo Clinic study “to assess the accuracy and safety of wearable devices in the endoscopy suite with patients undergoing procedures using anesthesia assisted sedation using smart watches”).

<sup>22</sup> ClinicalTrials.gov, “Comparison of Tissue Oxygenation Measurement Using Multimodal Devices” (last update posted Mar. 24, 2023), <https://clinicaltrials.gov/ct2/show/results/NCT05784103>.

<sup>23</sup> Fawzy A., Wu TD, Wang K., et al. Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients With COVID-19. *JAMA Intern Med.* 2022;182(7):730-738

<sup>24</sup> Apple Inc., *Blood Oxygen App on Apple Watch* at 8 (Oct. 2022), available at [https://www.apple.com/healthcare/docs/site/Blood\\_Oxygen\\_app\\_on\\_Apple\\_Watch\\_October\\_2022.pdf](https://www.apple.com/healthcare/docs/site/Blood_Oxygen_app_on_Apple_Watch_October_2022.pdf).

# APPENDIX A

# EXHIBIT 1



**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**Before the International Trade Commission**

**In the Matter of**

**CERTAIN LIGHT-BASED  
PHYSIOLOGICAL MEASUREMENT DEVICES  
AND COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**DECLARATION OF SUMBUL DESAI, M.D.**

1. My name is Sumbul Desai, M.D. I am over 21 years of age, of sound mind, and make this declaration voluntarily and based upon my own personal knowledge.

2. I received my M.D. from the Medical College of Virginia, VCU School of Medicine in 2008. I completed a residency in Internal Medicine at the Stanford University School of Medicine. During my residency, I was a Research Fellow in Public Policy at the Kaiser Family Foundation.

3. Since 2011, I have been on faculty at the Stanford University School of Medicine as a clinical associate professor. During my full-time tenure at Stanford, I served as the Vice Chair of Strategy and Innovation in the Department of Medicine, the Executive Director of the Stanford Center for Digital Health, and Associate Chief Medical Officer at Stanford Healthcare.

4. I am the Vice President of Health at Apple. In that role, I work every day to empower users with tools to improve their health. I oversee health initiatives that include clinical product development, medical research, and innovative clinical partnerships. I also lead the regulatory and quality teams at Apple. Across all these efforts, we leverage the latest health science to create innovative technology. We develop new products and services that give people everywhere actionable paths to healthier lives. And we bring together teams of experts — including designers, engineers, scientists, clinicians and more — who lend their unique insights on how we can have the greatest positive impact on the world.

5. Our work today builds on a longstanding commitment to the health space. For nearly a decade, Apple has devoted significant talent, resources, and expertise to designing, developing, and producing products and services aimed at giving users more information about their own health. We feel called to this work, first and foremost, because one of Apple's core

principles is a commitment to improve users' lives by developing the world's best technology. We also feel a responsibility to do this work because this is an area where Apple passionately believes it is uniquely suited to make a contribution to the world. We are proud to create products and services that are both innovative and user friendly, and we have a history of pioneering products that can change people's lives while fitting seamlessly into their days. When we apply that approach to health, we can play a meaningful role in improving health outcomes and encouraging people to live healthier lives. This includes users who purchase Apple products because of non-health-related functionalities and, through use, come to discover the Apple-developed health-related features. Apple believes that these efforts can lead to a better quality of life for users, and that by promoting earlier, preventive care, it can have the added benefit of reducing healthcare costs overall in the United States.<sup>1</sup> Most meaningfully of all, we have heard from hundreds of users who credit Apple's health features with improving their lives, and in many instances, saving them.

6. I understand Masimo and Cercacor have asserted five patents against Apple Watch Series 6 and 7 (and the now-released Apple Watch Series 8 and Ultra), alleging infringement by the Blood Oxygen feature in those models. I understand that on January 10, 2023, the Administrative Law Judge issued an initial determination finding a violation of Section 337 of the Tariff Act of 1930 based on infringement by Apple of one patent asserted by Masimo and Cercacor. I further understand that, on January 24, 2023, the Administrative Law Judge recommended excluding all Apple Watch products containing light-based pulse oximetry functionality from the United States.

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<sup>1</sup> K. Amadeo, "How Preventative Care Lowers Health Care Costs," *The Balance* (Oct. 28, 2022), <https://www.thebalance.com/preventive-care-how-it-lowers-aca-costs-3306074>.

7. This declaration is in support of Apple's efforts to show why an exclusion order in this Investigation would adversely impact public health and welfare for citizens throughout the United States. It is my understanding that an exclusion order would have the effect of preventing Apple's importation and sale of all Apple Watch models with the Blood Oxygen feature in the United States. Such an order would also, as a practical matter, preclude Apple from importing or selling current Apple Watch models with the FDA-approved electrocardiogram (ECG) app—a feature not accused of infringement in this Investigation, but which is available today only in current Apple Watch models with the Blood Oxygen feature—and would also prevent the sale of many Apple Watch models that support several other important wellness and healthcare features, such as the High Heart Rate Notification (HHRN) and Irregular Rhythm Notification (IRN), that are also not accused of infringement here. An exclusion order would therefore deprive the American public of numerous health benefits, including health benefits that have absolutely nothing to do with the patents asserted in this Investigation. It would also deprive them of other potentially life-saving features that are currently available to consumers, and would negatively impact public health and welfare by causing fewer users to seek out earlier medical diagnosis and treatment. This deprivation could result not only in certain people not having access to all the features available on Apple Watch currently, but could also result in the loss of U.S. lives that could have been otherwise avoided had Apple Watch with all its current features been available to them. Removing Apple Watch with all the current features it offers would actually be a step backwards with respect to users being able to monitor their health and seek out early medical treatment, if appropriate. Furthermore, an exclusion order could hamper the extensive medical research that is planned or already underway in the United States that relies on the health and wellness features in the accused Apple Watch models.

### **HEALTH FEATURES IN APPLE WATCH**

8. Apple has introduced many health-related hardware and software technologies from applications (apps) used on iPhone, including the Health app, apps used in healthcare settings on iPad, and the accused Apple Watch products.

#### **Blood Oxygen**

9. Since the release of the Apple Watch Series 6 in 2020, new Apple Watch models (except for the Apple Watch SE) have included the Blood Oxygen feature, which measures users' oxygen saturation of arterial hemoglobin ( $\text{SpO}_2$ ) using the photoplethysmogram (PPG) sensor array on the back of the Apple Watch. The PPG sensor array, which includes a combination of LED emitters and photodiodes, is also used for a variety of other measurements, such as heart rate. The measurement of blood oxygen saturation—which represents the percentage of arterial hemoglobin in red blood cells—is a well-established metric of overall wellness, and the Blood Oxygen feature is included in the Apple Watch for wellness and fitness applications. For example, the Blood Oxygen feature can be used to identify a user's baseline blood-oxygen measurements, which can (for example) be used to gauge a user's exertion at altitude.

10. The Blood Oxygen feature measures blood oxygen optically. Red and infrared LEDs in the Apple Watch's PPG sensor array emit light at different wavelengths. This light passes through and is attenuated by the tissue in the user's wrist, where the light is absorbed to different degrees by oxygenated and deoxygenated blood, and photodiodes in the PPG array then detect some of the light reflected by the user's tissue. The Blood Oxygen feature relies on the user's pulse to establish a baseline measurement and then uses the ratio of the detected red and infrared light to calculate the user's blood-oxygen saturation. Users can receive blood-oxygen measurements either on-demand (through the Blood Oxygen app) or through background measurements. For reliability, these blood-oxygen measurements are taken only when the user

satisfies certain posture requirements, *i.e.*, when the Apple Watch is roughly face-up on the user's wrist and the user is stationary.

11. The Blood Oxygen feature is the result of intensive efforts by Apple engineers, who created an accurate, reliable pulse oximeter that also satisfies the exacting design standards that distinguish Apple products. The functionality of the Blood Oxygen is based on a complex and tightly integrated set of hardware and software, which were developed internally at Apple. During development, Apple conducted multiple studies, involving hundreds of consenting participants, to test and refine the accuracy of the Blood Oxygen feature under a variety of conditions. Apple also validated the performance of the Blood Oxygen feature using reference procedures, confirming accuracy under standards set forth in the pulse oximeter International Standard and FDA Guidance.<sup>2</sup>

12. Importantly, during its testing and development process, Apple focused on ensuring that the Blood Oxygen feature would work equally well for people of all skin tones. It has long been reported that there may be racial disparities in the accuracy of pulse oximeters on the market. For example, a study published last year in the *Journal of the American Medical Association* (JAMA) suggested that “racial and ethnic biases in pulse oximetry accuracy were associated with greater occult hypoxemia in Asian, Black, and non-Black Hispanic patients with COVID-19, which was associated with significantly delayed or unrecognized eligibility for COVID-19 therapies among Black and Hispanic patients.”<sup>3</sup> To avoid similar disparities for

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<sup>2</sup> Apple Inc., *Blood Oxygen App on Apple Watch* (Oct. 2022), available at [https://www.apple.com/healthcare/docs/site/Blood\\_Oxygen\\_app\\_on\\_Apple\\_Watch\\_October\\_2022.pdf](https://www.apple.com/healthcare/docs/site/Blood_Oxygen_app_on_Apple_Watch_October_2022.pdf).

<sup>3</sup> Fawzy A., Wu TD, Wang K., et al., “Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients With COVID-19,” *JAMA Intern. Med.* 2022;182(7):730-738, available at <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653>.

wearers of Apple Watch, Apple validated the performance of Apple Watch across a wide range of skin tones. In October 2022, Apple released a white paper confirming that there is no “skin-tone dependence” in key metrics of accuracy.<sup>4</sup>

**Other Health Features, Including IRN and ECG**

13. Beyond the Blood Oxygen feature, the most recent versions of Apple Watch—Apple Watch Series 8 and Apple Watch Ultra—include a multitude of other wellness and health features, such as heart-rate tracking, fall detection, activity and workout tracking, sleep tracking, medication notifications, hand-washing reminders, and a “Medical ID” feature that allows first responders and emergency room staff to access critical medical information, such as name and emergency contact information, from a patient’s Apple Watch without compromising the user’s privacy. One new feature, introduced in 2022, is the ability to detect wrist temperature; tracking nightly changes in wrist temperature can provide insight into a user’s well-being, as wrist temperature can vary due to physiological factors such as menstrual cycles and illness. Wrist temperature measurements can also be used for retrospective ovulation estimates, which can be very important for many users.

14. Furthermore, the most recent versions of Apple Watch include two separate FDA-authorized software as a medical device (SaMD) features: (1) the PPG-based IRN feature, and (2) the ECG app. Both those features have been available on Apple Watch since they were introduced on Apple Watch Series 4 in 2018. Among the Apple Watch models currently sold by Apple, the ECG app is available only on the Apple Watch Series 8 and Ultra models—the same models that also feature the Blood Oxygen app. IRN feature and ECG app are each standalone

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<sup>4</sup> Apple Inc., *Blood Oxygen App on Apple Watch* (Oct. 2022), available at [https://www.apple.com/healthcare/docs/site/Blood\\_Oxygen\\_app\\_on\\_Apple\\_Watch\\_October\\_2022.pdf](https://www.apple.com/healthcare/docs/site/Blood_Oxygen_app_on_Apple_Watch_October_2022.pdf).

SaMDs. As explained below, IRN feature and ECG app each separately underwent extensive clinical validation studies during development to test for safety and effectiveness. IRN feature and ECG app each were granted marketing authorization separately by FDA as SaMDs through the de novo authorization process in 2018.

15. ECG app is a SaMD developed internally by Apple engineers and clinicians that allows a user to record a thirty-second, single-lead ECG on their Watch. This is a test that many people never receive in their lifetimes, even though its results can be clinically meaningful and, in some cases, potentially lifesaving. Apple has made ECGs much more widely available by leveraging an electrical heart sensor on Apple Watch, which can measure the small change in electrical potential caused by the depolarization of the heart muscles as those muscles contract. To measure this change in electrical potential, a user makes contact with two electrodes, which then measure the electrical potential between those electrodes. On Apple Watch, one of the electrodes is on the back of the case and makes contact with the wrist, the other electrode is on the crown of the Watch case. The user opens the ECG app and touches that electrode on the crown of the Watch case with a finger from the opposite arm to “close the electrical loop” and take an ECG. In this way, recording an ECG requires an affirmative act by the user to open the ECG app and make contact with the electrodes. The app’s algorithm on the Apple Watch then analyzes the electrical signals recorded to determine if the electrical signals show a normal heart rhythm, called Normal Sinus Rhythm, or if the electrical signals show signs of atrial fibrillation (AFib), which is the most common serious cardiac arrhythmia. The ECG app then provides a result of the analysis to the user on the Apple Watch, stores the ECG recording and result, and allows the user to log symptoms and convert that recording to a PDF to share with their healthcare provider.



16. IRN is a separate SaMD feature, also developed internally by Apple engineers and clinicians, which gives users insights into their heart rhythms. If the IRN feature identifies heart rhythms suggestive of AFib, it notifies the user and prompts them to seek medical attention. To create this feature, Apple leveraged the PPG sensor on the back of Apple Watch, which shines light into the skin near blood vessels and measures the amount of light reflected back using photodiodes. The IRN feature's algorithm attempts to take a one-minute PPG recording, called a tachogram, about every two hours, assuming conditions are appropriate for the tachogram measurement. The IRN feature's algorithm then uses the PPG recording to calculate a user's pulse rate, which can also provide information about their heart rhythm. Finally, the IRN feature analyzes the heart rhythm data captured from the PPG using an Apple developed algorithm to determine if the user's heart rhythms are suggestive of AFib. Notably, all this happens in the background. A user simply must enable the feature once, wear Apple Watch, and the IRN feature will automatically and periodically attempt to measure their heart rhythms.

17. In preparing its separate FDA authorization applications for ECG app and IRN feature, Apple conducted extensive clinical trials testing the safety and effectiveness of Apple's single-lead ECG and ECG app as measured against a traditional 12-lead ECG. Similarly, Apple conducted extensive clinical trials testing the safety and effectiveness of the IRN feature as measured against an ECG patch interpreted by a clinician.<sup>5</sup>

18. All currently available Apple Watches also include the HHRN feature.<sup>6</sup> This is a health feature that is not an FDA-authorized medical device or SaMD, as it does not provide any

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<sup>5</sup> See Apple Inc., *Using Apple Watch for Arrhythmia Detection* (Dec. 2020), available at [https://www.apple.com/healthcare/docs/site/Apple\\_Watch\\_Arrhythmia\\_Detection.pdf](https://www.apple.com/healthcare/docs/site/Apple_Watch_Arrhythmia_Detection.pdf).

<sup>6</sup> The HHRN feature was introduced with Apple Watch before the ECG app and IRN feature were introduced.

indication to a user of a suspected irregularity. Like the IRN feature, HHRN is a feature that works in the background to monitor a user's heart rate using the PPG sensor on the back of Apple Watch. Periodically, the HHRN feature will measure the user's heart rate and compare it to the user's perceived activity level, *i.e.*, motion. If there is an inconsistency between the user's heart rate, *i.e.*, a high heart rate, and the user's motion for at least ten consecutive minutes, the HHRN feature will provide a notice to the user that their heart rate rose above a predefined level for more than 10-minutes while the user appeared to be stationary. Notably, the user can set the heart rate (between 100bpm and 150bpm) that will trigger this notice.

### **Health Benefits to Consumers Using Apple Watch**

19. The health and wellness features described above provide substantial benefits to consumers. In addition to positive feedback Apple has received for Blood Oxygen app for promoted use cases like hiking at altitude, Apple has received letters and news reports about how the Blood Oxygen features have—according to the users themselves—incidentally improved and, in many instances, saved their lives.<sup>7</sup> For example, only a few months ago, a mother on a skiing vacation with her family in Colorado used the Blood Oxygen feature in her Apple Watch to determine that her son was suffering from low blood-oxygen levels—leading to his hospitalization and treatment for a life-threatening condition known as High Altitude Pulmonary Edema.<sup>8</sup>

20. Similarly, Apple Watch with ECG app and IRN feature provides a benefit to consumers in proactively alerting them to possible cardiovascular conditions, as well as other

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<sup>7</sup> Camryn Justice, “‘It saved my life’: Cleveland man credits Apple Watch for life-saving medical discovery,” News 5 Cleveland (Mar. 16, 2023), <https://www.news5cleveland.com/news/local-news/it-saved-my-life-cleveland-man-credits-apple-watch-for-life-saving-medical-discovery>.

<sup>8</sup> Marcella Lee, “How My Apple Watch Helped Save My Son’s Life,” CBS8 (Jan. 4, 2023), <https://www.cbs8.com/article/news/local/how-my-apple-watch-helped-save-my-son/509-58d3d68e-3d17-436d-8039-34268717be2f>.

# EXHIBIT 3

**Before the U.S. International Trade Commission**

**In the Matter of**

**CERTAIN LIGHT-BASED  
PHYSIOLOGICAL MEASUREMENT  
DEVICES AND COMPONENTS  
THEREOF**

Investigation No. 337-TA-1276

**Declaration of Michael A.M. Davies  
Concerning the Public Interest  
June 5, 2023**

## I. QUALIFICATIONS

1. My name is Michael A. M. Davies. I am over 21 years of age, of sound mind, and make this declaration based upon my expertise, experience, and knowledge, together with additional specific research and analysis as described below. My educational background, including my specialist expertise and relevant experience, is set out in detail in my curriculum vitae, which is attached to this report as Exhibit A.
2. I hold a Master of Arts degree in computer science, engineering, mathematics, and physics; a Master of Engineering in robotics, cybernetics (artificial intelligence), and microelectronics; and a Master of Business Administration (with Distinction), with a specialization in technology, innovation, and strategy. I have worked in various roles during my career—as an engineer, an executive, an entrepreneur in technology businesses, an educator, and as an expert witness.
3. I lead Endeavour Partners, which I founded. Endeavour Partners advises businesses, not-for-profit organizations and government agencies on technology, innovation, business strategy, and public policy issues.
4. For more than 15 years, I also have taught on these and related topics at Massachusetts Institute of Technology (MIT) and London Business School (LBS). I am a Senior Lecturer at MIT, and at LBS I serve as a Guest Lecturer.
5. Relevant to this Investigation, I was a Co-Founder, Executive, and Board Member of Zero360 from 2012 to 2015. Zero360 developed next-generation wearable devices with bio-sensing capabilities. Zero-360's platform was designed to integrate with both in-house and third-party wellness programs with the objective of detecting significant events and capturing valuable health data to drive behavioral changes and achieve improved health outcomes.

- [REDACTED]
- [REDACTED]
6. In addition, I was a Co-Founder and the Chief Technology Officer of EquuSys, an animal instrumentation company that commercialized my patented inventions and whose products provide real-time real-world data to enhance the evaluation, diagnosis, rehabilitation, training, and conditioning of animals.
  7. I am a Co-Founder and the Chief Executive Officer of WKD.SMRT, whose product is an electronic hardware, software, and services platform. WKD.SMRT provides superior data using artificial intelligence to de-risk and accelerate clinical trials. I have been and continue to be involved in designing, developing, testing, and building our products. In addition, as CEO, I manage the IT operations of this business, which include deployment and maintenance of in-house data servers and cloud services.
  8. My work in WKD.SMRT, Zero360, and EquuSys provided me with extensive experience developing mobile, wearable, and in-home devices to monitor and improve human health.
  9. I have served for over a decade as an expert witness in several legal matters, such as investigations, and litigation and arbitration proceedings involving intellectual property or public policy issues. I have delivered expert reports and declarations on the public interest in multiple Department of Justice cases. I have also been an expert witness, or submitted declarations, in several investigations undertaken by the International Trade Commission relating to smartphones, tablets, wearable devices, personal computers, computer servers and electronic components.
  10. I have worked on supply chain issues for more than 30 years for complex and sophisticated electro-mechanical devices, such as mobile phones, smartphones, smartwatches, and, more broadly, the Internet of Things. During this span, I have performed in-depth work with leading device

[REDACTED]

vendors, leading contract manufacturers, and leading component manufactures including Foxconn, Flex, and Samsung Electronics. I worked with vendors on how they evaluate their overall technology strategy; how they procure sub-systems and components as well as evaluate and select vendors; the tradeoffs between custom, state-of-the-art procurement strategies versus the using commodity components and multi-sourcing them; and on timing of investments involved in bringing new products to market, and in increasing the level of output.

11. For this declaration, I have been asked to assess the impact on the Public Interest of the possible exclusion of Apple Watches (the Requested Remedies) with the Blood Oxygen capability<sup>1</sup>.
12. I make the following statements based on 30-plus years' worth of specialist expertise and relevant experience, research, and knowledge of smartwatches, digital devices, microchip and sensor manufacturing, the related global supply chain, digital health tracking software, and the associated relevant business practices.
13. My opinions are also based on my familiarity with mobile devices and wearables, and with Apple's products in particular. I have worked with Apple mobile products for approximately 30 years, beginning with a project I pioneered and led in which Apple worked with Nokia and mobile network operator Bell South New Zealand (erstwhile Vodafone NZ and recently rebranded as One New Zealand) providing digital cellular connectivity for the Apple Newton in combination with the Nokia 2110 and the Nokia DataCard. In this role I was both the Head of Strategy and the Head of Research and Design; and since then I have continued to be a user of Apple's products. Beginning more than 15 years ago, much of my work has

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<sup>1</sup> See for example <https://support.apple.com/guide/watch/blood-oxygen-apdaf17aa5ef/watchos>

[REDACTED]

[REDACTED]

focused on the overall characteristics of Apple's business, its product strategy, technology strategy, R&D strategy and go-to-market strategy, and I have worked with a broad cross-section of device vendors and component vendors who compete with Apple or are partners of Apple.

## II. IMPACT OF REQUESTED REMEDIES

14. It is my opinion that Masimo's Requested Remedies, which seek to exclude from importation, distribution, marketing, sale, and support Apple Watch Series 6, 7, 8, and Ultra, would cause an immediate and massive shortfall in the supply of smartwatches available to U.S. consumers, and would thereby cause significant harm to the Public Interest. This shortfall of smartwatches would harm millions of U.S. consumers who depend on their smartwatch for health and fitness capabilities provided through monitoring and data-gathering, in combination with a broad variety of other capabilities that are important in many aspects of their daily lives.
15. In addition to the important health benefits that smartwatches provide, U.S. consumers also depend on their smartwatch for productivity benefits provided through, for example, sending text messages, making phone calls and video calls, being alerted by and responding to notifications, and accessing their calendar and contacts. What distinguishes and differentiates Apple Watch from other wearable devices is that Apple Watch provides health and welfare benefits to U.S. consumers who are motivated to purchase a smartwatch because of the productivity capabilities that it provides, yet those same consumers would not purchase a wearable device that only provides specialized health capabilities, such as Masimo's W-1™.
16. Masimo's Requested Remedies would harm both U.S. consumers who are existing users seeking to replace their device due to loss, damage, or functionality; and also those who are would-be adopters of smartwatches,



capabilities with communication and productivity capabilities. Many users of smartwatches will engage different capabilities for a broad range of daily activities and long-term goals involving both health and productivity.

23. Conversely, there are many models of wearable devices that are wrist-worn digital devices that have only certain specific, specialized capabilities. These specialized models may be functional substitutes for consumers primarily interested in a particular kind of monitoring, yet these models lack the combination of health capabilities with communication and productivity capabilities. Therefore, although these devices are wearables, they are not “smartwatches.”
24. For example, Masimo’s W1™ wearable is a niche product with highly specific specialized capabilities—despite its price being higher than the Apple Watch Series 8.<sup>5</sup> The W1™ tracks certain specific health data, which addresses the needs of specific market segments, such as people with specific chronic health conditions. Rather than a smartwatch, the W1™ is, as Masimo labels it, an “Advanced Health Tracking Watch.”<sup>6</sup>
25. **Cost** is an important factor in U.S. consumer requirements. Given the current state of available smartwatches in the United States, other smartwatches do not provide the same value as Apple Watch. Potential options such as the Galaxy or the Pixel smartwatches are available at a similar price point but lack equivalent capabilities, as demonstrated in Table 2, below. Other would-be substitutes, such as the Masimo W1™ at \$499 (plus subscription), the Garmin Forerunner at \$599, or the upcoming

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<sup>5</sup> The Masimo W1™ is priced at \$499 and also requires a subscription of at least \$7.99 per month, while the price for the Apple Watch Series 8 starts \$100 below this at \$399 (see <https://www.masimopersonalhealth.com/products/masimo-W1™> and <https://www.apple.com/shop/buy-watch/apple-watch>).

<sup>6</sup> <https://www.masimopersonalhealth.com/products/masimo-W1>

[REDACTED]  
[REDACTED]  
Masimo Freedom™ at \$999, cost more than the Accused Devices. The Apple Watch Series 8 starts at \$399.

26. **Volume** matters in determining whether any particular smartwatch could serve as a viable substitute for the Accused Devices because the substitute must be able to be made available at sufficient scale to effectively mitigate the effect of the exclusion of the Accused Devices. The required volume of devices is significant: Between 30% and 35% of U.S adult consumers now own a smartwatch or wearable,<sup>7,8</sup> and o [REDACTED]  
[REDACTED]

**A. U.S. consumers rely on many different smartwatch features**

27. The Accused Devices are not devices that have single-point functionality, such as monitoring a cardiovascular condition. Rather, the Accused Devices are multi-purpose technologies that are designed to provide a wide range of functionality, thereby enabling various diverse capabilities to meet the requirements of U.S. consumers. For many U.S. consumers, their smartwatch's utility comes from its ability to combine both health and productivity capabilities, while at the same time offering a broad array of capabilities.
28. With a cellular- or Wi-Fi-connected smartwatch, a user can send and receive texts, calls, and email; share health information with healthcare providers and family; access the Internet, their apps, and their calendar; stay current with news, weather, and sports; navigate with GPS; and stream music. Through its connectivity, a smartwatch user can also keep children

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<sup>7</sup> <https://datareportal.com/reports/digital-2023-deep-dive-the-rise-of-wearables>

<sup>8</sup> <https://cdn.newswire.com/files/x/3c/e9/d48aafa86cac1002ee98de669a22.pdf>

<sup>9</sup> [REDACTED]

and elderly family members safe through location and health alerts, such as Fall Detection.

29. Table 1 below, from a survey conducted by research firm Creative Strategies, demonstrates the weekly use by Apple Watch users of the various smartwatch capabilities.<sup>10</sup>

Table 1 *Apple Watch users' weekly use of features and capabilities*<sup>11</sup>

<b>Weekly Use of Features and Capabilities</b>	<b>% of Users</b>
Check messages	81%
Decline a call	80%
<b>Check activity details</b>	75%
<b>Workout tracking</b>	74%
<b>Check heartrate</b>	73%
Look at third-party app	66%
Use non-fitness third-party apps	61%
Check email	57%
Set a reminder	54%
Answer a call	51%
Use the watch to find iPhone	46%
Use Siri to send a text	42%
Check social media	40%
Use GPS	34%
Use a scribble feature to write a text	33%
Control a smart home device	31%

30. Were the Requested Remedies to prevail, U.S. consumers who have adopted the Apple Watch would be unable to replace their device if it were lost, no longer functioned, or no longer met their requirements and became obsolescent or obsolete. Therefore, excluding the Accused Devices would harm millions of U.S. consumers who have invested time, energy, and money into their own, personalized combination of devices.

<sup>10</sup> <https://www.cultofmac.com/581078/people-love-declining-phone-calls-on-their-apple-watches/>

<sup>11</sup> <https://www.cultofmac.com/581078/people-love-declining-phone-calls-on-their-apple-watches/>

**B. The Accused Devices have significant volumes**

31. U.S. consumers demonstrate their requirements for smartwatches through their past and current purchases. [REDACTED]
32. [REDACTED]
33. Given the current volumes other smartwatches such as Garmin, Samsung, and Google provide to U.S. consumers, they would be unable to increase production to the extent required to mitigate the sudden and massive shortfall due the constraints of the supply chain for smartwatches.
34. Such mitigation of the sudden and massive shortfall in supply would require very significant increases in production from current levels. Garmin, Samsung, and Google would need to increase their output several-fold.
35. The constraints of the supply chain for smartwatches, for which I provide details below, mean that any increase in output levels sufficiently large to mitigate a substantial shortfall in supply would take a significant amount of time. As a result, it is extraordinarily unlikely if not impossible that the shortfall in supply that would result from the Requested Remedies could be mitigated within a commercially reasonable time.

12 [REDACTED]

48. Masimo has announced plans to launch another wearable in fall 2023, the Masimo Freedom™.<sup>24</sup> Like W1™, the Freedom™ would be a specialized niche device with health-monitoring features. Like W1™, the Freedom™ would fail to provide the communications and productivity capabilities that the Accused Devices provide to U.S. consumers. Although information about Freedom's™ complement of features has not yet been made available, the currently known differences between Freedom™ and W1™, as compared to Apple Watch, are that Freedom™ will require no subscription; Freedom™ will provide fall detection; and the price of Freedom™ will be double (\$999) what the W1™ costs (\$499).<sup>25</sup>
49. Masimo admits that their consumer watch offerings are not intended as a general-purpose smartwatch. In a recent quarterly earnings call, Masimo CEO Joe Kiani, while referring to Masimo's watches, stated:

As I've said before our customers that we're targeting are **people who have chronic illnesses** and need a serious monitor - that serious measurement - and they want it in a way that's unobtrusive.<sup>26</sup>

#### **IV. THE ACCUSED DEVICES PLAY A VITAL ROLE IN MEDICAL RESEARCH THAT CANNOT READILY BE REPLICATED**

##### **A. Apple makes significant investments and has powerful positive impacts in medical research**

50. Apple Watch serves a critical role in the medical research landscape. Its importance comes from its combination of functionality, capabilities, and performance, all of which account for its widespread adoption by U.S. consumers.

<sup>24</sup> <https://www.masimoconsumer.com/>

<sup>25</sup> <https://www.masimoconsumer.com/>; <https://www.masimopersonalhealth.com/products/masimo-w1>

<sup>26</sup> <https://events.q4inc.com/attendee/205736497/guest> (emphasis added).

51. The Accused Devices' hardware, software, and open-source platform capabilities allow for decentralized and minimally invasive studies which are easy, quick, and lower cost for researchers, while also being significantly more inclusive and accessible for study participants than conventional trials.<sup>27</sup> The breadth of functionality and of consumer usage creates unprecedented opportunities in medical research.
52. Apple Watch is designed not only to track health metrics at an individual level, but to be a vehicle for large scale medical research as well. This research is generally implemented through Apple's ResearchKit, an open-source framework which allows developers to create program interfaces based on the collection of user data. ResearchKit allows for visual consent flows, which allows users to remotely consent to study participation. It can also be used for surveys. Building on Apple HealthKit and CareKit's tracking, centralization, and remote transmission of data, ResearchKit can be used to prompt a user or study participant to perform a dynamic task. Researchers and developers are also able to program custom tests and tasks, thereby harnessing the power of the smartwatch's functionality to collect topic-specific health metrics.<sup>28</sup>
53. Traditionally, trial participants have typically been required to physically travel to a given location, often on a regular basis. When recruiting a participant pool intended to be fully representative of the target population, these physical requirements have been a major limiting factor. Additionally, in studies conducted on patient populations with certain conditions, there may be health implications to travel which prevent or restrict patient

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<sup>27</sup> <https://www.fda.gov/about-fda/oncology-center-excellence/advancing-oncology-decentralized-trials>; <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices>

<sup>28</sup> <https://medium.com/kinandcartacreated/introductions-healthkit-researchkit-and-carekit-d72e2ac9ce2>

[REDACTED]

participation and contribute to high rates of drop-out and poor rates for follow-up. For example, almost 20% of oncology trials fail due to low recruitment, and one of the most significant factors for low accrual is distance from a clinic, along with participants' financial situation and health insurance obstacles, all of which may be mutually reinforcing.<sup>29</sup>

54. ResearchKit and CareKit have negated many of those obstacles today. In conjunction with Apple Watch's health tracking functions, as implemented through application and study-specific software, the collective information generated by Apple Watch is remotely transmittable. The Apple Watch provides data at significantly more frequent intervals than traditional medical research and conventional approaches to clinical trials. Remote collection and transmission of data is a critical function used by researchers to transcend the limitations of traditional clinical trials and make unprecedented contributions to public and patient health.

**B. The widespread adoption by U.S. consumers of the Accused Devices benefits medical research**

55. The Accused Devices' widespread adoption by consumers is one of the most important dimensions of their position in medical research, and one which cannot readily be replicated. Apple Watches are popular consumer devices that combine health capabilities with communications and productivity capabilities, and are purchased for a variety of reasons. As a result, the user base of U.S. consumers who have the Accused Devices is comprised of people with all levels of health and wellness, ranging from no or minimal medical conditions, through undiagnosed conditions, to chronic and acute conditions.

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<sup>29</sup> <https://www.fdamap.com/about-20-per-cent-of-cancer-clinical-trials-fail-due-to-low-patient-recruitment.html>

56. This diversity of existing users has important implications for medical research, particularly in combination with the broadened scope of study enrollment and frequent data collection allowed by remote transmission and device wearability. Researchers utilize the Accused Devices to study population-level impacts of wearable devices and their health features on preventative treatment and early and intervention.<sup>30</sup>

57. For example, the American Heart association has stated:

As prevalent consumer devices owned for reasons other than just their cardiac-data-related technologies, the user population is sufficiently large and representative of the subjects researchers seek to recruit, that they allow studies to be fully enrolled cost-effectively, facilitating research the AHA promotes. Additionally, the Devices and their users allow for types of research to occur that might not otherwise be attempted, or only attempted less frequently or with smaller sample sizes. Notably, they facilitate research into whether cardiac health outcomes can be improved by consumer devices detecting and triggering interventions. As the novelty of these devices has waned since their introduction, researchers benefit from and, to some extent, rely on the extent of consumer adoption of the Devices to design and recruit for research studies.<sup>31</sup>

**C. The ECG and SpO2 features on Accused Devices provide significant value for research and public health**

58. The ECG feature on Apple Watch has been FDA-authorized under Class II classification since 2018.<sup>32</sup> The functionality of this feature was powerfully affirmed during the COVID-19 public health emergency, when the FDA published guidance explicitly expanding and encouraging the use of certain technologies, including the ECG app, to assist in diagnosis and

<sup>30</sup> <https://medium.com/kinandcartacreated/introductions-healthkit-researchkit-and-carekit-d72e2ac9ce2>

<sup>31</sup> Public Interest Statement of Non-Party American Heart Association

<sup>32</sup> <https://www.fiercebiotech.com/medtech/new-apple-watch-receives-fda-clearance-for-built-ecg>



management of conditions by healthcare professionals.<sup>33</sup> The ECG feature is also critical to numerous medical studies.

59. Many health studies are leveraging the ECG and SpO2 capabilities of the Accused Devices that are not available in the Apple Watch SE, or other devices such as the Masimo W1™.
60. The Mayo Clinic is currently undertaking a study with 1 million participants studying how Apple Watch ECG data can be assessed by Artificial Intelligence algorithms for better prediction of heart disease.<sup>34</sup> The Mayo Clinic is also working with the FDA to use the Apple Watch ECG with a wide range of other features to study how to improve outcomes for patients with heart failure.<sup>35</sup>
61. The American Heart Association is studying a drug with potential to treat atrial fibrillation, or AFib, by leveraging the ECG capabilities of the Accused Devices.<sup>36</sup>
62. Northwestern University and Johns Hopkins received a \$37 million grant for a seven-year study of stroke prevention and reducing the need for blood thinners among people with AFib by leveraging Apple Watch's ECG feature as well as its other sensors. "If proven effective, this new treatment paradigm will fundamentally change the standard of care for the millions of Americans living with AFib," said principal investigator Rod Passman, M.D., Northwestern Medicine's director of the Center for Arrhythmia Research and the Jules J. Reingold Professor of Electrophysiology. "Many of these patients are on blood thinners for the rest of their lives even if they

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<sup>33</sup> [https://www.apple.com/healthcare/docs/site/Apple\\_ECG\\_app\\_during\\_COVID-19.pdf](https://www.apple.com/healthcare/docs/site/Apple_ECG_app_during_COVID-19.pdf)

<sup>34</sup> <https://clinicaltrials.gov/ct2/show/NCT05324566>

<sup>35</sup> <https://clinicaltrials.gov/ct2/show/NCT04191356>

<sup>36</sup> <https://clinicaltrials.gov/ct2/show/NCT04433091>

have infrequent episodes of atrial fibrillation,” Passman said. “If we can show this strategy is equally protective against stroke and reduces bleeding, that could save lives, reduce cost and improve quality of life.”<sup>37</sup>

63. Anthem Blue Cross Blue Shield and the University of California, Irvine, are using the SpO2 measurement feature of Apple Watch, along with many other health tracking features, to study how to improve asthma management. Rajeev Ronanki, Chief Digital Officer at Anthem, said, “Millions of Americans are struggling with their asthma condition each day and we’re thrilled to collaborate with UCI, Apple and CareEvolution on studying new solutions.”<sup>38</sup>
64. The COVID-19 pandemic made clear the racial bias of many commercially available pulse oximeters.<sup>39</sup> Contrary to these products and competing wearable devices, the Apple Watch Series 6, 7, 8 and Ultra models’ pulse oximeter technology were specifically designed and tested to ensure that results were not compromised by racial bias.<sup>40</sup>
65. Asthma has been recognized for years as disproportionately affecting poor and minority communities, and as an issue of racial and environmental justice.<sup>41,42</sup> In the case of the Anthem and UC Irvine asthma study detailed above, disenfranchised communities stand to benefit from the results of accessible and diverse trial recruitment, especially as complemented by

<sup>37</sup> <https://appleinsider.com/articles/22/08/29/new-apple-watch-study-aims-to-cut-blood-thinner-use-by-afib-patients>; <https://breakthroughsforphysicians.nm.org/northwestern-awarded-first-ever-national-grant-to-study-wearables-stroke-prevention-in-patients-with-atrial-fibrillation.html>

<sup>38</sup> <https://news.uci.edu/2020/09/16/anthem-uci-will-investigate-how-digital-tools-can-aid-asthma-management/>

<sup>39</sup> <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653>

<sup>40</sup> [https://www.apple.com/healthcare/docs/site/Blood\\_Oxygen\\_app\\_on\\_Apple\\_Watch\\_October\\_2022.pdf](https://www.apple.com/healthcare/docs/site/Blood_Oxygen_app_on_Apple_Watch_October_2022.pdf)

<sup>41</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6042867/>

<sup>42</sup> <https://aafa.org/asthma-allergy-research/our-research/asthma-disparities-burden-on-minorities/>

pulse oximetry technology that is better able to self-correct for skin color than others on the market.<sup>43</sup>

**D. Various medical research is at risk in the event the Requested Remedies prevail**

66. The largest study ever conducted on Parkinson's disease, with 10,000 participants, was conducted with the ResearchKit-designed mPower app.<sup>44</sup> 93% of trial participants had never participated in a study before.

67. A study of AFib published in the New England Journal of Medicine had 419,297 participants leveraging an Apple Watch. According to the study's Conclusions:

This site-less (no on-site visits were required for the participants), pragmatic study design provides a foundation for large-scale pragmatic studies in which outcomes or adherence can be reliably assessed with user-owned devices.<sup>45</sup>

68. This study is important as AFib can often show no symptoms, and about 700,000 people in the United States alone may have AFib and not know it.<sup>46</sup>

69. An Apple Heart and Movement study with the American Heart Association studied 500,000 people used Apple Watch sensors to identify factors or early warning signs that impact heart health or mobility.<sup>47</sup>

70. A study with Nightware used the Apple Watch to address nightmare disorders associated with post-traumatic stress. The study monitored the

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<sup>43</sup> [https://www.apple.com/healthcare/docs/site/Blood\\_Oxygen\\_app\\_on\\_Apple\\_Watch\\_October\\_2022.pdf](https://www.apple.com/healthcare/docs/site/Blood_Oxygen_app_on_Apple_Watch_October_2022.pdf)

<sup>44</sup> <https://www.apple.com/lae/researchkit/>

<sup>45</sup> <https://www.nejm.org/doi/10.1056/NEJMoa1901183>

<sup>46</sup> <https://www.webofscience.com/wos/woscc/full-record/WOS:000429791900022?SID=USW2EC0D3CU1Lq4JY6XtCADXotLHT>

<sup>47</sup> <https://clinicaltrials.gov/ct2/show/NCT04198194>

sleeping patients via Apple Watch, which would vibrate when sensing a nightmare to disrupt the event without waking the participant.<sup>48</sup>

71. A Stanford study used Apple Watch to improve care for spine surgery patients. Previously it was impossible for surgeons to track mobility of patients before and after surgery. According to the study's

Intervention/treatment:

The Apple Watch and App are used for this study to record patient's mobility information (e.g., step counts, heart rate, stairs climbed, distance traveled) as well as provide an additional platform for patients to complete questionnaires.<sup>49</sup>

72. The studies mentioned above used Apple Watch for research into a range of different health issues, including asthma, Parkinson's, AFib, heart disease, nightmares, strokes, post-operative treatment, and general health and mobility. Those studies involved almost 2 million participants.

Therefore, excluding the Accused Devices would have a significant and

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<sup>48</sup> <https://clinicaltrials.gov/ct2/show/NCT03828656>

<sup>49</sup> <https://clinicaltrials.gov/ct2/show/NCT04379921>

negative impact on medical research. As Dr. Russell Bowler stated in his declaration:

A key feature of consumer devices is their integration of multiple sensors and particularly oxygen saturation (SpO2) for patients with respiratory diseases. In these patients from our research studies and personally my research group has found the Apple Watch to be an exceptional device that accurately measures important parameters such as heart rate, physical activity, and oxygen saturation. Coupled with monitoring apps, these parameters help predict the onset of acute illness. The devices are also significantly less expensive than research only devices and depriving consumers of the devices might unnecessarily limit access to remote medical monitoring in underserved groups (e.g., rural patients) who do not have ready access to specialists.<sup>50</sup>

## **V. THE ACCUSED DEVICES PROVIDE U.S. CONSUMERS WITH SIGNIFICANT HEALTH, WELLNESS, AND SAFETY BENEFITS**

### **A. Apple Watch can alert users to latent medical conditions**

73. The Apple Watch includes two FDA-authorized health apps: ECG and irregular heart rhythm notification (IRN).<sup>51</sup> These are authorized as “software as a medical device” (SaMD)<sup>52</sup>, and both can provide health-supporting and sometimes life-saving measurements of a user’s heart function.
74. An ECG can help diagnose many common heart problems, such as arrhythmias and coronary artery disease, as well as help monitor the effectiveness of heart disease treatments.<sup>53</sup> While some other

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<sup>50</sup> Letter “Support for the Apple Watch for use in tracking physiologic features in medical patients.” from Dr. Russell Bowler M.D., PhD., Director of COPD Clinic and Precision Medicine and Professor of Medicine of National Jewish Health

<sup>51</sup> <https://www.apple.com/newsroom/2018/12/ecg-app-and-irregular-heart-rhythm-notification-available-today-on-apple-watch/>

<sup>52</sup> <https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd>

<sup>53</sup> <https://www.mayoclinic.org/tests-procedures/ekg/about/pac-20384983>

smartwatches have FDA-authorized ECG monitoring, Apple Watch is the only general-purpose smartwatch with continuous monitoring that requires no user participation.<sup>54</sup>

75. As IRN runs in the background of Apple Watch, a user may be alerted to a heart condition they otherwise would not know they had, such as AFib, which can lead to a stroke or heart attack. More than 454,000 hospitalizations occur each year where AFib is the primary diagnosis, yet the condition frequently goes undetected for lack of clear symptoms.<sup>55</sup>
76. Such IRN alerts may have saved thousands of lives. For example, in the Stanford Apple Heart Study, 2,161 of the 400,000 participants were alerted by their Apple Watch of an irregular heart rhythm. Of those who received irregular notifications, 1,376 responded to a 90-day survey, and over 57% of these participants chose to seek medical attention they would not have otherwise sought and obtained.<sup>56</sup>
77. There are other instances where IRN alerts are attributed to saving lives. In one case, a Maine resident received an alert and sought medical care that revealed a tumor on her heart. She underwent five hours of open-heart surgery at a Boston hospital. The patient's surgeon assessed that she would have had "a massive stroke and died" if left untreated.<sup>57</sup>
78. In another case, a woman felt tightness in her chest while her Apple Watch indicated a heart rate of 169 beats per minute. Tests revealed a blockage in her coronary arteries that was later successfully cleared in surgery.<sup>58</sup> In yet

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<sup>54</sup> <https://pocketnow.com/best-smartwatches-for-ecg/>

<sup>55</sup> [https://www.cdc.gov/heartdisease/atrial\\_fibrillation.htm](https://www.cdc.gov/heartdisease/atrial_fibrillation.htm)

<sup>56</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8112605/>

<sup>57</sup> <https://www.today.com/health/womens-health/heart-tumor-apple-watch-atrial-fibrillation-rcna39993>

<sup>58</sup> <https://www.wzzm13.com/article/news/health/norton-shores-woman-credits-apple-watch-for-detecting-heart-condition/69-6b2db4b5-2d3f-47f0-a069-2d0961bbec4b>

another case, a teenage boy received an alert that his heart rate was spiking, which led to an eight-hour corrective surgery.<sup>59</sup> In contrast, Samsung Watch does not currently detect AFib.<sup>60</sup>

**B. Health and wellness tracking by Accused Devices is enabled by their wide range of sensors and capabilities, in particular relative to specialized single-purpose devices**

79. The Masimo W1™ watch is a specialized device designed for users with specific medical requirements from their wearable. In comparison, the Accused Devices are constructed to meet a wide range of consumer requirements. Because of their more robust range of functionality and support for broader and deeper capabilities, the Accused Devices include several more sensors and capabilities than Masimo's watch.
80. The Masimo W1™ can monitor SpO2 levels, pulse rate, heartrate, relative level of hydration, relative strength of pulse, pleth variability, sleep, and respiration rate.<sup>61</sup>
81. In comparison, the newest of the Accused Devices, the Series 8 and the Ultra, have the following features: emergency calling, fall detection, crash detection, SpO2 sensor and app, electrical heart sensor, optical heart sensor, temperature sensor, ECG, heartrate notifications, irregular heart rhythm notification, sleep stage tracking, and fertility cycle tracking.<sup>62</sup> The Accused Devices also feature over 20,000 third-party apps to further meet the health and productivity requirements of U.S. consumers.<sup>63</sup>

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<sup>59</sup> <https://kfor.com/news/stratford-teen-spreads-heart-health-awareness-after-apple-watch-notifies-him-of-heart-rate/>

<sup>60</sup> <https://www.pcmag.com/news/samsung-galaxy-watch-gets-fda-clearance-to-monitor-for-afib>

<sup>61</sup> <https://www.masimopersonalhealth.com/products/masimo-w1>

<sup>62</sup> <https://www.apple.com/watch/compare/>

<sup>63</sup> <https://www.techradar.com/best/best-apple-watch-apps-2022>

82. The integration of the health data registered by the variety of sensors on the devices, along with complementary apps, shows how valuable having a wide range of capabilities is for wearable devices to health and wellness. Apple CareKit is a platform for creating apps that connect patients with healthcare professionals, and with their medical records.<sup>64</sup> Additionally, Apple HealthKit is a data repository for health and fitness data that can be integrated with a user's medical records.<sup>65</sup> Both of these are available and used with the Accused Devices.
83. By contrast, there are an assortment of Android apps that offer medical, fitness, and personal well-being features. In most cases, these apps are not pre-installed on Android smartwatches but rather must be uploaded, posing integration and data portability challenges to their users.
84. Samsung Health, a health tracking app that centralizes user data, comes loaded on some, but not all, Samsung Galaxy Watches. But Samsung Health does not integrate with many other apps and therefore lacks the broad scope of Apple Health's data-sharing capability.<sup>66</sup>
85. It is difficult to overstate the importance of having health features installed on a smartwatch as shipped and active by default. Many elderly users, and even many younger ones, experience steep learning curves when it comes to using mobile technology. Locating apps, installing them, and optimizing the settings can be difficult tasks. Apple Watch default settings provide instant and effortless health monitoring, as well as make a vastly complex device extremely user-friendly.

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<sup>64</sup> <https://www.apple.com/lae/researchkit/>

<sup>65</sup> <https://developer.apple.com/documentation/healthkit>



86. A user of one of the Accused Devices can synthesize the health data from the variety of sensors and capabilities to assess their overall health to a greater extent than the narrower view provided by the Masimo watches.

**C. The Accused Devices provide significant accessibility benefits for U.S consumers**

87. Americans with disabilities and special needs benefit from the use of the Accused Devices. According to CDC data, there are over 60 million adults in the United States who live with one or more disabilities.<sup>67</sup> As a company, Apple is motivated by a decades-long commitment that “accessibility is a fundamental human right.”<sup>68</sup> The Accused Devices contain many accessibility features for users with vision, hearing, and physical disabilities. Nothing in the Masimo W1™ user manual indicates any accessibility features for persons living with disabilities.<sup>69</sup>
88. For example, Apple’s VoiceOver gives users with low or no vision the option to hear what is on the watch’s screen in over 45 compatible languages.<sup>70</sup> For users with difficulty operating the devices using a touchscreen, the user can operate an onscreen motion pointer or answer calls using clench, double clench, and pinch gestures.<sup>71</sup>
89. In keeping with the step counters popular on smartwatches, the Accused Devices also encourage wheelchair users to set “roll goals,” and enables

<sup>67</sup> <https://www.cdc.gov/ncbddd/disabilityandhealth/infographic-disability-impacts-all.html>

<sup>68</sup> <https://www.imore.com/apple-accessibility-human-right>

<sup>69</sup>

<https://manuals.plus/m/0feb8f87d57dc7d90b7e5a44292c639d8c1b62a49e787e6bb389d3e53936306c.pdf>

<sup>70</sup> <https://support.apple.com/en-us/HT204576>

<sup>71</sup> <https://support.apple.com/en-us/HT212760>

other family members.<sup>82</sup> For parents and caregivers, a cellular-enabled Apple Watch with Family Setup allows their children and teenagers to stay connected without a smartphone. This allows parents to view their child's location, monitor their contacts, and provide emergency funds through Apple Cash.<sup>83,84</sup>

97. Cellular-enabled smartwatches can be life-changing and potentially life-saving for older adults in the United States, a demographic of approximately 73 million; another approximately 365,000 U.S. consumers turn 65 each year.<sup>85</sup> The security of a cellular-enabled wrist device equipped with Family Setup functions such as locator capabilities, movement monitoring, and fall detection/alerts can facilitate greater independence for the wearer and offer peace of mind to their loved ones.
98. In addition to those features available on all Apple Watches, the Apple Watch Ultra has a feature to turn on a siren that can be heard from 600 feet away.<sup>86</sup> This siren can be used to signal for help in an emergency.
99. Exclusion of the Accused Devices could have potentially life-threatening consequences for U.S. consumers as access to these important safety features would become unavailable.

**E. The Requested Remedies would mean the loss of continuous health-data tracking for existing users**

100. Under an Exclusion Order, current users of the Accused Devices would be unable to replace their lost, stolen, or nonfunctioning smartwatch with a device that meets their requirements, as the Accused Devices would no

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<sup>82</sup> <https://www.epiwatch.com/home#anchor-1>

<sup>83</sup> <https://support.apple.com/en-us/HT211782>

<sup>84</sup> <https://support.apple.com/en-us/HT211768>

<sup>85</sup> <https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html>

<sup>86</sup> <https://support.apple.com/en-us/HT213438>

longer be available. Those users would be unable to continuously track important health data as they had in the past, or to access the Accused Devices' distinct health-enhancing and life-saving features.

## **VI. THE REQUESTED REMEDIES WOULD HAVE A SIGNIFICANT ADVERSE IMPACT ON THE U.S. ECONOMY**

### **A. The Requested Remedies would impact U.S. employment**

101. The Requested Remedies, if granted, would have far-reaching impacts on the U.S. economy. According to Apple's most recent data, its "job footprint" equals 2.4 million jobs across all 50 states: 90,000 direct jobs and an anticipated 110,000 in 2023; 450,000 jobs through its 9,000 U.S. suppliers and manufacturers; and 1.9 million jobs in the app economy.<sup>87</sup> Apple's U.S. job footprint extends to many professions, including but not limited to software and hardware engineers, app developers, designers, scientists, manufacturing, construction, retail, customer support, and marketing.<sup>88</sup>
102. Apple's 2020 Supplier List, the most recent available, includes companies from across the United States, many of them manufacturers: Alabama (3M); Arizona (Intel); California (IDEMIA, II-VI Inc., Microchip Tech. Inc., Pegatron Corp., Renesas, Skyworks); Colorado (Broadcom, Microchip Tech. Inc.); Florida (Qorvo); Georgia (Solvay); Idaho (ON Semiconductor Corp.); Illinois (II-VI Inc.); Indiana (SABIC Innovative Plastics); Iowa (3M); Kentucky (Corning); Maine (ON Semiconductor Corp., Texas Instruments); Massachusetts (Intel, Skyworks, Wickedder); Minnesota (3M, Henkel); New Hampshire (Henkel); New Jersey (II-VI Inc.); New Mexico (Intel); North Carolina (Qorvo); Ohio (3M, Solvay); Oregon (Alpha & Omega Semiconductor, Intel, Maxim, ON Semiconductor Corp., Qorvo);

<sup>87</sup> <https://www.apple.com/newsroom/2019/08/apples-us-job-footprint-grows-to-two-point-four-million/>

<sup>88</sup> <https://www.apple.com/job-creation/>

Pennsylvania (II-VI Inc., ON Semiconductor Corp.); South Carolina (3M); Tennessee (Flex); Texas (Flex, Foxconn, II-VI Inc., Qorvo, Samsung, Texas Instruments, Wistron); and Wisconsin (3M, TDK). Additionally, Apple also sources components from companies who contract out manufacturing with headquarters in California (AMD, Lumentum, Parade Technologies Inc., Synaptics) and Texas (Cirrus Logic).<sup>89</sup>

103. In 2022, Apple reported “Wearables, Home, and Accessories” as its second-highest revenue-generating product line, behind the iPhone.<sup>90</sup> As this important revenue stream diminished under an Exclusion Order, Apple’s broad impact on the U.S. economy would be felt by downstream suppliers and developers, as well as in potential layoffs.

**B. An Exclusion Order would hamper U.S. consumers’ adoption of smartwatch technology**

104. U.S. consumers have adopted wearable technology at a relatively quick rate. In 2016, approximately 9 million smartwatches were sold in the United States, whereas 21 million were sold four years later in 2020.<sup>91</sup> According to Pew Research Center, 21% of Americans were using smartwatches or other wearable fitness trackers in 2020.<sup>92</sup> In looking at the recognized technology adoption cycle personality types—innovators (2.5%), early adopters (13.5%), early majority (34%), late majority (34%), and laggards (16%)<sup>93</sup>—smartwatches have entered the early majority phase where ownership expands into a broader demographic.

<sup>89</sup> <https://www.apple.com/supplier-responsibility/pdf/Apple-Supplier-List.pdf>

<sup>91</sup> <https://www.statista.com/statistics/381696/wearables-unit-sales-forecast-united-states-by-category/>

<sup>92</sup> <https://www.pewresearch.org/fact-tank/2020/01/09/about-one-in-five-americans-use-a-smart-watch-or-fitness-tracker/>

<sup>93</sup> <https://www.interaction-design.org/literature/article/understanding-early-adopters-and-customer-adoption-patterns>

UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.

Before the Honorable Monica Bhattacharyya  
Administrative Law Judge

In the Matter of

CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND  
COMPONENTS THEREOF

Inv. No. 337-TA-1276

**NOTICE OF DENIAL OF RESPONDENT APPLE INC.'S REQUESTS FOR  
REHEARING OF DECISIONS DENYING INSTITUTION  
OF INTER PARTES REVIEW FOR U.S. PATENT NO. 10,945,648**

Complainants Masimo Corporation and Cercacor Laboratories, Inc. (collectively, “Masimo”) respectfully submit this notice to advise the Commission of recent decisions by the Patent Trial and Appeal Board (the “Board”) of the United States Patent and Trademark Office concerning U.S. Patent No. 10,945,648 (the “’648 Patent”). The ’648 Patent, along with U.S. Patent Nos. 10,912,501 (the “’501 Patent”) and 10,912,502 (the “’502 Patent”), are the Poeze Patents asserted in this Investigation.

Respondent Apple Inc. (“Apple”) filed six petitions for *inter partes* review of the Poeze Patents. The Board denied institution of all six petitions because it found that Apple failed to meet its burden to show a reasonable likelihood of success that any challenged claim was unpatentable. Apple requested rehearing of the Board’s denials of institution for all six petitions. On June 22 and 23, 2023, the Board denied Apple’s requests for rehearing for the petitions challenging the ’648 Patent. Copies of the Board’s decisions are attached hereto as Exhibits A-B. Further, as Masimo previously informed the Commission, Apple’s requests for rehearing for the ’501 and ’502 Patent petitions were denied by the Board on May 17, 2023. EDIS Doc. ID 797853 at 2-3, Exs. 45-48. Accordingly, Masimo respectfully advises the Commission that the Board has now

denied all six of Apple's rehearing requests. In view of the Board's denial of all six of Apple's rehearing petitions, Apple's IPRs petitions challenging the '501, '502, and '648 Patents have concluded and are final, without any right to appeal.

Dated: June 23, 2023

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Cercacor Laboratories, Inc.*

**In the Matter of Certain Light-Based Physiological Measurement Devices  
and Components Thereof  
Inv. No. 337-TA-1276**

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on June 23, 2023, I caused copies of the foregoing document to be filed and served as indicated below:

Secretary – U.S. International Trade Commission	
The Honorable Katherine M. Hiner Acting Secretary to the Commission U.S. International Trade Commission 500 E Street, SW, Room 112 Washington, DC 20436	<input checked="" type="checkbox"/> Via Electronic Filing [EDIS] <input type="checkbox"/> Via hand delivery <input type="checkbox"/> Via Express Delivery <input type="checkbox"/> Not filed
Administrative Law Judge – U.S. International Trade Commission	
The Honorable Monica Bhattacharyya U.S. International Trade Commission 500 E Street, S.W., Room 317 Washington, D.C. 20436	<input checked="" type="checkbox"/> Via E-mail to edward.jou@usitc.gov and Bhattacharyya337@usitc.gov
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June 23, 2023

/s/ Claire A. Stoneman  
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# EXHIBIT A

**Appx27007**

[Trials@uspto.gov](mailto:Trials@uspto.gov)  
571-272-7822

Paper 17  
Date: June 22, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APPLE INC.,  
Petitioner,

v.

MASIMO CORPORATION,  
Patent Owner.

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IPR2022-01275  
Patent 10,945,648 B2

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Before JOSIAH C. COCKS, NEIL T. POWELL, and  
JAMES A. TARTAL, *Administrative Patent Judges*.

POWELL, *Administrative Patent Judge*.

DECISION  
Denying Petitioner's Request For Rehearing of Decision Denying Institution  
of *Inter Partes* Review  
37 C.F.R. § 42.71(d)

IPR2022-01275  
Patent 10,945,648 B2

## I. INTRODUCTION

Petitioner Apple Inc. (“Petitioner”) timely filed a Request for Rehearing (Paper 16, “Req. Reh’g”) of our Decision denying institution of *inter partes* review (Paper 15, “Decision” or “Dec.”) based on Petitioner’s Petition (Paper 3, “Pet.”). We denied institution of *inter partes* review because we determined that Petitioner had not met its burden to show that there was a reasonable likelihood of success that Petitioner would prevail in its contention that at least one of claims 1–30 of U.S. Patent No. 10,945,648 (“the ’648 patent”) (“the challenged claims”) was unpatentable.

For the reasons stated below, we deny Petitioner’s Request for Rehearing.

## II. ANALYSIS

“Inter partes review shall not be instituted unless the Board decides that information presented in the petition demonstrates that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable.” 37 C.F.R. § 42.108(c). When rehearing a decision on a petition, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). The burdens and requirements of a request for rehearing are stated in 37 C.F.R. § 42.71(d):

(d) Rehearing. . . . The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, a reply, or a sur-reply.

Here, it is Petitioner’s burden to show that we misapprehended or overlooked any matter in deciding not to institute an *inter partes* review.

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We address below, in the order presented in the Request for Rehearing, the matters that Petitioner raises that it contends merit rehearing.

*A.*

Petitioner first contends that, in our Decision, we overlooked certain disclosure in Aizawa<sup>1</sup> as to a configuration of a holder. Req. Reh’g 1–6. Specifically, Petitioner contends that “the Decision errs in apparently overlooking that this ‘configuration’ is simply that of the holder *disclosed in Aizawa itself*, and the Petition’s integration of Aizawa’s holder into Mendelson merely retains these disclosed features.” *Id.* at 3. Petitioner is of the view that the Decision reflects some requirement for Petitioner to provide “further reasons to motivate this configuration” and somehow holds Petitioner “to a standard higher than that required by the law.” *Id.* Petitioner proceeds to reproduce various annotated figures from the Petition that Petitioner reiterates constitutes its view as to what a person of ordinary skill in the art would have arrived at based on “the Petition’s prior art combinations” proposed in alleging the unpatentability of claims of the ’648 patent. *See id.* at 3–6. Petitioner concludes that the “motivations” offered in the Petition in accounting for features of the challenged claims were “legally sufficient” and that “[i]t was error for the Board to have required additional motivations for the retained features beyond those already offered for the holder and its retained features.” *Id.* at 5–6.

In the Decision, we expressed our view as to the sufficiency of Petitioner’s argument concerning the supposed holder configuration that

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<sup>1</sup> U.S. Patent Application Publication No. US 2002/0188210 A1 published Dec. 12, 2002 (“Aizawa,” Ex. 1007).

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Petitioner contends emerges from the combined teachings of Mendelson<sup>2</sup>, Aizawa, and Ohsaki<sup>3</sup>. *See, e.g.*, Dec. 16–20. To that end, in determining whether a reasonable likelihood of prevailing had been shown, we were not persuaded that the figures created by Petitioner, and the accompanying argument, sufficiently supported what Petitioner argued a skilled artisan would have derived from the combined teachings of the prior art. We did not impose some type of elevated standard requiring any “further reasons to motivate” the combination of Mendelson, Aizawa, and Ohsaki. Rather, we determined that Petitioner had not met its burden to show what was necessary as to the alleged unpatentability of the challenged claims to warrant institution of a trial. Petitioner’s reproduction of some of those figures in its Request for Rehearing, and reiteration of associated arguments, does not demonstrate that we misapprehended or overlooked any matter as a part of our Decision in reaching that determination. That Petitioner may disagree with our determination is simply not a proper basis for seeking rehearing.

*B.*

Petitioner next argues that we overlooked “critical errors” said to be associated with Patent Owner’s arguments challenging Petitioner’s proposed grounds of unpatentability. Reg. Reh’g 6. In that respect, Petitioner contends that the “skepticism” expressed in the Decision as to the adequacy of Petitioner’s proposed reasons for combining the teachings of the prior art

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<sup>2</sup> U.S. Patent No. US 6,801,799 B2 issued Oct. 5, 2004 (“Mendelson” or “Mendelson-799,” Ex. 1006).

<sup>3</sup> U.S. Patent Application Publication No. US 2001/0056243 A1 published Dec. 27, 2001 (“Ohsaki,” Ex. 1008).

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is based on arguments offered by Patent Owner that are “imbued with legal and factual errors.” *Id.* Petitioner proceeds to reargue some of those reasons, focusing, in particular, on the theory that Ohsaki’s teachings applied to “the Mendelson/Aizawa device” would have provided for “improved adhesion” between a user’s wrist and the sensor’s surface. *Id.* at 6–10.<sup>4</sup>

As Petitioner notes, in our Decision we determined that Petitioner had not explained adequately that a skilled artisan would have sought to provide additional modifications to the proposed detector based on the combination of Mendelson and Aizawa to further include features associated with Ohsaki’s board shape. *See* Req. Reh’g 6; Dec. 20 (“Nor has Petitioner explained adequately why a skilled artisan would have assessed that Petitioner’s reasoning applies to a protrusion configured to have specific characteristics, e.g., multiple distinct openings that are unaffiliated with adhesion or comfort.”). In so determining, we found persuasive Patent Owner’s arguments, and the testimony of Patent Owner’s declarant (Dr. Duckworth), challenging Petitioner’s grounds on this point. Dec. 20 (citing Preliminary Response (Paper 10) 28–33, 59–61, 67–69; Ex. 2002 ¶¶ 109–111, 122–126). Petitioner now attempts to reemphasize arguments made in the Petition (and by Petitioner’s declarant, Dr. Kenny). *See, e.g.*, Req. Reh’g 6–10. We, however, previously considered those arguments and found them unavailing when taken alongside the countervailing arguments offered by Patent Owner and its declarant. Once again, we note that Petitioner’s disagreement with our determinations based on the record that

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<sup>4</sup> Petitioner also submits that its arguments also apply to its proposed grounds involving reference Kotanagi (PCT Application No. WO 2005/092182 A1 published Oct. 6, 2005 (Ex. 1015, 1016)) in lieu of Ohsaki. *See* Req. Reh’g 10.

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was before us does not demonstrate that we misapprehended or overlooked any matter in connection with that record.

*C.*

Petitioner additionally argues that we overlooked disclosure in Scharf as to transparent windows and configurations therefor in declining to institute trial. Req. Reh’g 10–12. As Petitioner notes, in the Decision, we were not satisfied that Petitioner had explained adequately why Scharf’s teachings would have led a skilled artisan to position “windows over the openings of a convex protrusion in the manner urged by Petitioner,” and also why “the teachings on which Petitioner relies give rise to the particular window configuration required by the claims.” Dec. 23. Petitioner clearly disagrees with our assessment, but does not suitably identify any matter that we misapprehended or overlooked in so making that assessment.

Moreover, as our Decision notes, even if we agreed with Petitioner’s arguments about Scharf and windows in the proposed prior-art combination, those arguments would not cure the above-discussed deficiencies in Petitioner’s arguments about a convex protrusion. Dec. 23. Accordingly, any oversight or error regarding the windows would not negate our determination that Petitioner did not demonstrate a reasonable likelihood of prevailing with respect to at least one of claims 1–30 of the ’648 patent.

*D.*

Petitioner additionally challenges our determination in the Decision that Petitioner’s proposed grounds were premised on impermissible hindsight. Req. Reh’g 13–15. To that end, Petitioner contends that (1) the Decision “overlooks record evidence of several distinct and relied-upon



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motivations from within the prior art” (*id.* at 13–15), and (2) the Decision “overlooks the complete absence of record evidence demonstrating Petitioner reliance on the ’648 Patent disclosure” (*id.* at 15).

With respect to item (1), Petitioner contends that the Petition and Petitioner’s declarant “identify at least four motivations for the modification (i.e., improved adhesion, comfort, detection efficiency, and component protection), but the Decision acknowledges only two (i.e., improved adhesion and comfort).” Req. Reh’g 14. Petitioner, thus, is of the view that the Decision overlooked “the related motivations regarding improvements to detection efficiency and component protection.” *Id.*

We note initially that the Petition focused on discussion of alleged “improved adhesion” as a central reason for combining the teaching of Mendelson, Aizawa and Ohsaki.<sup>5</sup> Our concern with that reasoning warranted particular discussion in the Decision. Nevertheless, we did not overlook any contemplated “motivations” offered by Petitioner as proposed bases for combining the teachings of the prior art. Rather, we found them unpersuasive to arrive at the particular configuration of a detector proposed by Petitioner as allegedly emerging from the proposed prior art combination of Mendelson, Aizawa, and Ohsaki. As we expressed in the Decision “we find questionable Petitioner’s and Dr. Kenny’s assessment and reasoning as to what a skilled artisan would have understood from the teachings of

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<sup>5</sup> See, e.g., Pet. 21–22 (“[a person of ordinary skill in the art] would have modified Mendelson-799 and Aizawa’s sensor to include Ohsaki’s protrusion ***comprising a convex surface***. The combined structure would have prevented slippage and improved adhesion between a subject’s wrist and a surface of the sensor”); *id.* at 24 (“a [person of ordinary skill in the art] would have improved the adhesion provided by a flat protrusion . . . by adding a convex surface . . . as disclosed in Ohsaki.”).

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Mendelson-799, Aizawa, and Ohsaki as proposed by Petitioner here.”

Dec. 20. We, instead, found persuasive Patent Owner’s arguments, supported by Dr. Duckworth, that Petitioner’s assessments as to the proposed prior art combination were a product of impermissible hindsight analysis. *Id.* (citing Preliminary Response 30–34; Ex. 2002 ¶¶ 109–111, 122–126). Our determination as to the persuasiveness of Patent Owner’s arguments is not a result of any matter being misapprehended or overlooked.

With respect to item (2) referenced above, Petitioner is of the view that there is no “evidence” present in the record that Petitioner relied on disclosure of the ’648 patent in connection with its proposed grounds. Reg. Reh’g 15. It is not entirely clear what “evidence” Petitioner regards as absent. As expressed in the Decision, we were not persuaded that the bases underscoring any of Petitioner’s proposed grounds arose from only assessment of the teachings of the prior art. Rather, we regarded that assessment as one premised on an intent to reach the features of the challenged claims rather than being based simply on knowledge derived by a skilled artisan from the prior art. In that respect, Petitioner’s citation to *In re McLaughlin* is inapt, as we concluded that Petitioner’s hindsight reasoning was based on more than simply knowledge within the level of ordinary skill in the art. *See* Reg’ Reh’g 15 (quoting *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971)) (“[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art . . . and does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper.”)

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### III. CONCLUSION

We have considered Petitioner's Request for Rehearing of our determination not to institute an *inter partes* review based on the Petition presented in this proceeding. Because we determine that Petitioner has not shown that we misapprehended or overlooked any matters in denying institution, we deny Petitioner's Request for Rehearing.

### IV. ORDER

It is

ORDERED that Petitioner's Request for Rehearing is *denied*.

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Patent 10,945,648 B2

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# EXHIBIT B

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571-272-7822

Paper 17  
Date: June 23, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APPLE INC.,  
Petitioner,

v.

MASIMO CORPORATION,  
Patent Owner.

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IPR2022-01276  
Patent 10,945,648 B2

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Before JOSIAH C. COCKS, NEIL T. POWELL, and  
JAMES A. TARTAL, *Administrative Patent Judges*.

POWELL, *Administrative Patent Judge*.

DECISION

Denying Petitioner's Request For Rehearing of Decision Denying Institution  
of *Inter Partes* Review  
37 C.F.R. § 42.71(d)

IPR2022-01276  
Patent 10,945,648 B2

## I. INTRODUCTION

Petitioner Apple Inc. (“Petitioner”) timely filed a Request for Rehearing (Paper 16, “Req. Reh’g”) of our Decision denying institution of *inter partes* review (Paper 15, “Decision” or “Dec.”) based on Petitioner’s Petition (Paper 2). We denied institution of *inter partes* review because we determined that Petitioner had not met its burden to show that there was a reasonable likelihood of success that Petitioner would prevail in its contention that at least one of claims 1–30 of U.S. Patent No. 10,945,648 B2 (“the challenged claims”) was unpatentable.

For the reasons stated below, we deny Petitioner’s Request for Rehearing.

## II. ANALYSIS

“Inter partes review shall not be instituted unless the Board decides that information presented in the petition demonstrates that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable.” 37 C.F.R. § 42.108(c). When rehearing a decision on a petition, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). The burdens and requirements of a request for rehearing are stated in 37 C.F.R. § 42.71(d):

(d) Rehearing. . . . The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, a reply, or a sur-reply.

Here, it is Petitioner’s burden to show that we misapprehended or overlooked any matter in deciding not to institute an *inter partes* review.

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Petitioner characterizes its Request for Rehearing as identifying three sources of error in the Decision. *See, e.g.*, Req. Reh’g 1–2. We address below, in the order presented in the Request for Rehearing, the matters that Petitioner raises that it contends merit rehearing.

*A.*

Petitioner first contends that, in our Decision, we overlooked certain disclosure in Lumidigm.<sup>1</sup> Req. Reh’g 1, 2–5. Specifically, Petitioner contends that “the Decision errs in demanding that the Petition offer reasons to motivate arranging aspects of Lumidigm into a configuration that Lumidigm itself already teaches, namely its opaque protrusion having openings associated with photodiodes.” *Id.* at 1. Petitioner proceeds to reiterate some arguments from the Petition regarding Petitioner’s views of what Lumidigm’s teachings taken with Scharf<sup>2</sup> and Kotanagi<sup>3</sup> would have suggested to a skilled artisan. *Id.* at 2–5. Contrary to Petitioner’s argument, however, our Decision did not demonstrate “misapprehension” of Petitioner’s proposed modifications to Lumidigm’s sensor. *See, e.g., id.* at 5. In that respect, we did not impose any burden on Petitioner to provide a reason to arrange aspects of Lumidigm into a configuration that Lumidigm already teaches. Rather, we simply were not persuaded that the composite

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<sup>1</sup> U.S. Patent No. 7,620,212 B1 issued Nov. 17, 2009 (“Lumidigm,” Ex. 1006). Although Jeffrey G. Allen is listed as the first named inventor of U.S. Patent No. 7,620,212 B2, Lumidigm, Inc. is listed as the Assignee. *See* Ex. 1006, code (73). We, as do the parties in their briefings in this proceeding, refer to the noted patent as “Lumidigm.”

<sup>2</sup> U.S. Patent No. 6,330,468 B1 issued Dec. 11, 2001 (“Scharf,” Ex. 1025).

<sup>3</sup> PCT Application No. WO 2005/092182 A1 published Oct. 6, 2005 (“Kotanagi,” Ex. 1007 (English translation)).



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figures offered by Petitioner, as purportedly the result of a combined device arising from Lumidigm's, Kotanagi's, and Scharf's teachings, arose "based on an objective assessment of what those teachings would have conveyed to a skilled artisan." *See, e.g.*, Dec. 17–19. Although Petitioner may disagree with our conclusion, disagreement is not a proper basis for seeking rehearing. To that end, our expressed skepticism of Petitioner's approach coupled with our determination that Patent Owner had the better argument simply does not demonstrate that we misapprehended or overlooked any matter.

*B.*

Petitioner next argues that "the Decision errs in finding that the Petitioner does not adequately explain why a [person of ordinary skill in the art] would have been motivated to perform the proposed modifications to Lumidigm's sensor based on Kotanagi and Scharf." Reg. Reh'g 1, 5–14. Although Petitioner styles this as a separate section from that noted above, and separates this section into three subsections (labeled "A.,"<sup>4</sup> "B.,"<sup>5</sup> and "C."<sup>6</sup>), Petitioner essentially takes the same inadequate approach as noted above. Namely, Petitioner expresses disagreement with our assessment of

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<sup>4</sup> "The Decision overlooks express teachings in Lumidigm that motivate changing the shape of Lumidigm's protrusion to a convex shape based on Kotanagi." Reg. Reh'g 6–7.

<sup>5</sup> "The Decision overlooks Lumidigm's express disclosure of protrusion with openings made from recesses in 'optically opaque material' to reduce light piping." Reg. Reh'g 8–11.

<sup>6</sup> "The Decision overlooks Lumidigm's express teaching that its sensor head can include 'optical relays,' such as 'fiber optic face plates,' which were relied upon to motivate the proposed modifications based on Scharf." Reg. Reh'g 11–13.

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the persuasiveness, or lack thereof, in the Petition’s proposal as to what the combined teachings of the relevant references would have conveyed to a person of ordinary skill in the art. In expressing that disagreement, Petitioner essentially reproduces many of the arguments, and composite figures, that were initially presented in the Petition, and, in effect, simply asks that we now find those same arguments persuasive. We previously considered those arguments, but when taken alongside Patent Owner’s countervailing view, supported by the testimony of its declarant (Dr. Duckworth), we found them unavailing. *See, e.g.*, Dec. 15–19. That Petitioner desires a different outcome simply does not warrant rehearing.

We do note in particular that in the Decision, we considered each of the arguments that Petitioner contends we “overlook[ed]” as a part of the noted sections “A.,” “B.,” and “C.” in the Request for Rehearing. *See, e.g., id.* As we expressed in the Decision, we were skeptical that Petitioner’s proposed composite figures of alleged prior art teachings constituted an objective assessment of what would have been actually suggested to a skilled artisan. Petitioner does not now present any credible argument that our skepticism was a product of some matter overlooked or misapprehended.

C.

Lastly, Petitioner challenges our determination in the Decision that Petitioner’s proposed grounds were premised on impermissible hindsight. Req. Reh’g 2, 13–15. In doing so, Petitioner generally disputes that its proposed combination of prior art teachings was the result of impermissible hindsight, and discounts content of Patent Owner’s Preliminary Response (Paper 10, “POPR”) that was cited in the Decision. *See, e.g.*, Req. Reh’g at 13–15 (citing Dec. 16, 18, 19; POPR 26–28). The reasoning for our

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determination that Petitioner's proposed rationale in challenging the patentability of the challenged claims was insufficient is set forth in our Decision. *See* Dec. 15–19. Although Petitioner evidently believes its rationale has merit, and correspondingly believes Patent Owner's countervailing arguments are lacking, those beliefs do not present a situation where rehearing is appropriate.

### III. CONCLUSION

We have considered Petitioner's Request for Rehearing of our determination not to institute an *inter partes* review based on the Petition presented in this proceeding. Because we determine that Petitioner has not shown that we misapprehended or overlooked any matters in denying institution, we deny Petitioner's Request for Rehearing.

### IV. ORDER

It is

ORDERED that Petitioner's Request for Rehearing is *denied*.

IPR2022-01276  
Patent 10,945,648 B2

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**UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.**

**In the Matter of**

**CERTAIN LIGHT-BASED  
PHYSIOLOGICAL MEASUREMENT  
DEVICES AND COMPONENTS  
THEREOF**

**Investigation No. 337-TA-1276**

**ORDER DENYING RESPONDENT’S MOTION TO STAY REMEDIAL ORDERS  
PENDING APPEAL AND/OR IN LIGHT OF POTENTIAL GOVERNMENT  
SHUTDOWN**

On August 18, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”), based on a complaint filed on behalf of Masimo Corporation and Cercacor Laboratories, Inc., both of Irvine, California (collectively, “Complainants”). *See* 86 Fed. Reg. 46275 (Aug. 18, 2021). The complaint, as amended, alleged violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,912,501 (“the ’501 patent”); U.S. Patent No. 10,912,502 (“the ’502 patent”); U.S. Patent No. 10,945,648 (“the ’648 patent”); U.S. Patent No. 10,687,745 (“the ’745 patent”); and U.S. Patent No. 7,761,127 (“the ’127 patent”). *Id.* The amended complaint further alleged that an industry in the United States exists and/or is in the process of being established as required by section 337. *Id.* The notice of investigation named Apple Inc. of Cupertino, California (“Apple”) as the sole respondent. *Id.* at 46276. The Office of Unfair Import Investigations did not participate in this investigation. *Id.*

Before the presiding administrative law judge (“ALJ”) issued the final initial determination (“Final ID”), Complainants withdrew from the investigation certain asserted patent claims. *See* Order No. 25 (Mar. 23, 2022), *unreviewed* by Comm’n Notice (Apr. 12, 2022); Order No. 33 (May 20, 2022), *unreviewed* by Comm’n Notice (June 10, 2022). At the time of the Final ID, only claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claims 12, 24, and 30 of the ’648 patent, claims 9, 18, and 27 of the ’745 patent, and claim 9 of the ’127 patent remained in the investigation. Claim 18 of the ’745 patent remained at issue for purposes of the domestic industry only.

On January 10, 2023, the ALJ issued the Final ID, which found that Apple violated section 337 as to claims 24 and 30 of the ’648 patent, but not as to claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claim 12 of the ’648 patent, claims 9 and 27 of the ’745 patent, and claim 9 of the ’127 patent. *See, e.g.*, Final ID at 335–36.

On May 15, 2023, the Commission determined to review the Final ID in part. *See* 88 Fed. Reg. 32243, 32243–46 (May 19, 2023). The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. *See id.*

On October 26, 2023, the Commission issued its final determination in this investigation, finding Apple in violation of section 337 as to only claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent. 88 Fed. Reg. 75032, 75032–33 (Nov. 1, 2023). The Commission issued: (1) a limited exclusion order prohibiting the importation of light-based physiological measurement devices and components thereof that infringe one or more of claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent; and (2) a cease and desist order directed to Apple. *Id.* The Commission determined that the public interest factors did not preclude issuance of the limited exclusion order or the cease and desist order. *Id.* The

Commission further determined that no bond was to be required during the period of Presidential review. *See id.*; 19 U.S.C. 1337(j)(3).

On October 30, 2023, Apple filed a motion to stay the exclusion and cease and desist orders pending appeal and/or in light of a potential government shutdown. On November 9, 2023, Complainants filed an opposition to Apple's motion.

Upon review of Apple's motion and Complainants' response thereto, it is hereby ORDERED that:

- (1) Apple's motion to the stay exclusion and cease and desist orders pending appeal and/or in light of a potential government shutdown is denied; and
- (2) Notice of this Order shall be served on the parties to this investigation.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', enclosed within a large, loopy oval shape.

Lisa R. Barton  
Secretary to the Commission

Issued: December 20, 2023

Certain Light-Based Physiological Measurement Devices and Components Thereof; Inv.  
No. 337-TA-1276 (Violation)

337-1276 Violation

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the parties listed have entered an appearance in the above captioned investigation, and a copy of the PUBLIC CERTIFICATE OF SERVICE was served upon the following parties via first class mail and air mail where necessary.

Document	Security	Document Type	Official Rec'd Date	Title
810738	Public	Order, Commission	12/20/2023 01:54 PM	Order Denying Respondent's Motion to Stay Remedial Orders Pending Appeal and/or in Light of Poten...

Service Date: December 20, 2023

/s/

\_\_\_\_\_  
Lisa R. Barton  
U.S. International Trade Commission  
500 E Street, S.W.  
Suite 112  
Washington, D.C. 20436



Certain Light-Based Physiological Measurement Devices and Components Thereof; Inv.  
No. 337-TA-1276 (Violation)

337-1276 Violation

CERTIFICATE OF SERVICE

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On behalf of Complainant Cercacor Laboratories, Inc.;Masimo  
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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.

In the Matter of

CERTAIN LIGHT-BASED  
PHYSIOLOGICAL MEASUREMENT  
DEVICES AND COMPONENTS  
THEREOF

Investigation No. 337-TA-1276

COMMISSION OPINION DENYING RESPONDENT’S MOTION TO STAY THE  
REMEDIAL ORDERS

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**PUBLIC VERSION****I. INTRODUCTION**

On October 26, 2023, the Commission issued its final determination in this investigation, finding Apple Inc. of Cupertino, California (“Apple”), the sole respondent, in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, as to certain claims of U.S. Patent No. 10,912,502 (“the ’502 patent”) and U.S. Patent No. 10,945,648 (“the ’648 patent”). 88 Fed. Reg. 75032, 75032–33 (Nov. 1, 2023). The Commission issued: (1) a limited exclusion order (“LEO”) prohibiting the importation of light-based physiological measurement devices and components thereof that infringe one or more of those claims; and (2) a cease and desist order (“CDO”) directed to Apple. *Id.* Thereafter, Apple filed a motion to stay the LEO and CDO pending appeal and/or in light of a potential government shutdown. Masimo Corporation (“Masimo”) and Cercacor Laboratories, Inc. (collectively, “Complainants”) filed an opposition to this motion. For the reasons discussed herein, Apple’s motion is denied.

**II. BACKGROUND**

The Commission instituted this investigation on August 18, 2021, based on a complaint filed by Complainants on June 30, 2021, with an amended complaint filed on July 12, 2021, and supplemented on July 19, 2021. 86 Fed. Reg. 46275 (Aug. 18, 2021). The amended complaint alleged violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of the ’502 and ’648 patents as well as U.S. Patent No. 10,912,501 (“the ’501 patent”); U.S. Patent No. 10,687,745 (“the ’745 patent”), and U.S. Patent No. 7,761,127 (“the ’127 patent”). *Id.* The notice of investigation named Apple as the sole respondent. *Id.* at 46276. The Office of Unfair Import Investigations did not participate in this investigation. *Id.*

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Before the presiding administrative law judge (“ALJ”) issued the final initial determination (“Final ID”), Complainants withdrew certain asserted patent claims from the investigation. *See* Order No. 25 (Mar. 23, 2022), *unreviewed* by Comm’n Notice (Apr. 12, 2022); Order No. 33 (May 20, 2022), *unreviewed* by Comm’n Notice (June 10, 2022). At the time of the Final ID, only claim 12 of the ’501 patent; claims 22 and 28 of the ’502 patent; claims 12, 24, and 30 of the ’648 patent; claims 9, 18, and 27 of the ’745 patent; and claim 9 of the ’127 patent remained in the investigation.

On October 26, 2023, the Commission found that Apple violated section 337 as to claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent and issued an LEO and CDO. 88 Fed. Reg. 75032, 75032–33 (Nov. 1, 2023). The Commission determined that the public interest factors did not preclude issuance of the remedial orders. *See id.*; 19 U.S.C. § 1337(j)(3).

On October 30, 2023, Apple filed the pending motion to stay the remedial orders pending appeal and/or in light of a potential government shutdown. *See* Respondent Apple Inc.’s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, EDIS Doc. ID 807326 (Oct. 30, 2023) (“Motion” or “Mtn.”). On November 9, 2023, Complainants filed an opposition to Apple’s motion. *See* Complainants’ Opposition to Respondent Apple Inc.’s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, EDIS Doc. ID 808262 (Nov. 9, 2023) (“Oppn.”).<sup>1</sup>

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<sup>1</sup> On November 20, 2023, Complainants filed Complainants’ Request for Judicial Notice of Recent Regulatory Developments for Masimo W1 Watch. EDIS Doc. ID 808970 (Nov. 20, 2023). Complainants asked the Commission to consider, in making its determination on Apple’s Motion, a decision of the United States Food and Drug Administration related to Masimo’s W1

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## III. LEGAL STANDARD

The Administrative Procedure Act provides an agency with the authority to “postpone the effective date of action taken by it, pending judicial review” if the “agency finds that justice so requires.” 5 U.S.C. § 705. The Federal Circuit has set forth the following four-part test to assess whether to stay a lower court’s remedy pending appeal:

(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether the issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

*Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990)

(quotation omitted). The factors are subject to weighing, and each factor need not be given equal weight. *See id.* at 512–13.

The Commission evaluates motions for stay pending appeal under the *Standard Havens* test, with one exception. The Commission has recognized the futility of establishing a likelihood-of-success for a movant given that it is difficult to ask an agency to find its own decision is likely to be overturned on appeal. *See Certain Agric. Tractors Under 50 Power Take-Off Horsepower*, Inv. No. 337-TA-380, Comm’n Op. Denying Respondents’ Petition for Reconsideration and Motion for Relief Pending Appeal at 10 (Apr. 24, 1997) (“*Agric. Tractors*”) (denying respondents’ motion to stay a general exclusion order and cease and desist orders and discussing *Wash. Metro. Area Transit Comm. v. Holiday Tours, Inc.*, 559 F.2d 841, 844–45 (D.C. Cir. 1977)). Thus, in lieu of the *Standard Havens* “likely to succeed on the merits” factor,

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Watch product and documents associated with that decision. *See id.* at 1–2. However, putting aside the applicability of judicial notice for the documents in question, the Commission does not rely on these documents and consideration of them would not alter the Commission’s determination.

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the Commission considers whether it has “ruled on an admittedly difficult legal question.” *See Certain Tobacco Heating Articles & Components Thereof*, Inv. No. 337-TA-1199, Comm’n Op. Denying Respondents’ Motion to Stay Limited Exclusion Order and Cease and Desist Orders Pending Appeal at 4 (Jan. 20, 2022) (“*Tobacco Heating Articles*”); *see also Holiday Tours*, 559 F.2d at 844–45 (“What is fairly contemplated is that tribunals may properly stay their own orders when they have ruled on an admittedly difficult legal question and when the equities of the case suggest that the status quo should be maintained.”). As the Commission stated in *Tobacco Heating Articles*, it has “repeatedly recited and applied this ‘admittedly difficult question’ test in previous investigations in which stays of its remedial orders were sought pending appeal.” Comm’n Op. at 4 (footnote collecting investigations omitted).

**IV. APPLE’S MOTION AND ANALYSIS THEREOF****A. The *Standard Havens* Factors****1. Admittedly Difficult Legal Questions**

Apple presents three separately-alleged “admittedly difficult legal questions,” discussed below, *see* Motion at 6–18; the Commission finds that none of these is admittedly difficult.

**a. Domestic Industry—Whether a Patent-Practicing Article Must Exist at the Time the Complaint is Filed**

According to Apple, “[b]y affirming the ALJ’s conclusion that Complainants ‘have shown the existence of a domestic industry,’ Comm’n Op. at 67, the Commission necessarily held that Section 337’s requirement that an industry ‘relating to the articles protected by the patent . . . exists’ . . . is satisfied even if the only article described in the complaint is a drawing of an imaginary product.” Mtn. at 6–7 (footnote omitted). Apple asserts that “this ruling is wrong in light of the Federal Circuit’s ruling in *Microsoft Corp. v. ITC* that ‘a company seeking section 337 protection must . . . provide evidence’ that ‘relates to an *actual article* that practices

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the patent, regardless of whether or not that article is manufactured domestically or abroad.” *Id.* at 7 (quoting *Microsoft Corp. v. Int’l Trade Comm’n*, 731 F.3d 1354, 1361–62 (Fed. Cir. 2013)) (Apple’s emphasis). Apple further argues that, “[a]t the very least, this case presents the difficult question [of] whether Complainants identified an ‘actual article’ within the meaning of the statute.” *Id.*; *see also id.* at 7–12.

Apple has not shown that this is an “admittedly difficult legal question” at least because, as Complainants point out, Apple is challenging a simple factual finding of the Commission (and the Final ID). *See Oppn.* at 9–13. The Commission did not find that a domestic industry exists based on a drawing of an imaginary product, as Apple alleges. Nor did the Commission base its finding on a product that did not exist at the time the complaint was filed. Apple’s motion ignores the evidentiary record and the Final ID’s and the Commission’s findings, which reflect the existence of, as of the filing of the complaint, numerous Masimo Watch articles and extensive related documentation, testimony, and investments. *See, e.g.,* Final ID at 56–85; *see also Oppn.* at 10–13.

**b. Prosecution Laches**

Apple argues that “Complainants’ conduct in this case falls squarely within the doctrine of prosecution laches, which bars them from receiving any relief on the asserted claims.” *Mtn.* at 12 (citing *Personalized Media Commc’ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023)). Apple points out that “[l]aches applies if ‘(1) the patentee’s delay in prosecution . . . [is] unreasonable and inexcusable under the totality of the circumstances,’ and ‘(2) the accused infringer . . . suffered prejudice attributable to the delay.’” *Id.* (quoting *Personalized Media*, 57 F.4th at 1354). For the first element, Apple argues that “Complainants delayed for twelve years in filing the asserted claims—with no clear reason for doing so other than strategic gamesmanship.” *Id.*; *see also id.* at 12–14. For the second element, Apple asserts that it suffered

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significant prejudice because it “invested in, worked on, or used the claimed technology during the period of delay.” *Id.* at 14 (quoting *Personalized Media*, 57 F.4th at 1357).

Apple has not shown an “admittedly difficult legal question” because Apple waived its opportunity to challenge this issue by not properly presenting it in its petition for review of the Final ID. *See* Oppn. at 13. With respect to the content of such a petition, the Commission’s Rules require, in part, that “[t]he petition for review must set forth a concise statement of the facts material to the consideration of the stated issues, and must present a concise argument providing the reasons that review by the Commission is necessary or appropriate to resolve an important issue of fact, law, or policy.” 19 C.F.R. § 210.43(b)(2). Furthermore, this subsection specifies:

Petitions for review may not incorporate statements, issues, or arguments by reference. Any issue not raised in a petition for review will be deemed to have been abandoned by the petitioning party and may be disregarded by the Commission in reviewing the initial determination (unless the Commission chooses to review the issue on its own initiative under § 210.44), and any argument not relied on in a petition for review will be deemed to have been abandoned and may be disregarded by the Commission.

*Id.*

Here, Apple improperly incorporated its argument by reference from its post-hearing briefing, which is not sufficient to raise the issue before the Commission. *See* Respondent Apple Inc.’s Petition for Review of the Initial Determination of Violation of Section 337, EDIS Doc. ID 788470, at 78–79, 99–100 (“RPet.”); 19 C.F.R. § 210.43(b)(2); *Tobacco Heating Articles*, Comm’n Op. at 10 (denying a motion to stay remedial orders and finding that the argument “raised now by Philip Morris comes far too late, and the Commission deems it abandoned”); *Hazani v. U.S. Int’l Trade Comm’n*, 126 F.3d 1473, 1476–77 (Fed. Cir. 1997) (finding argument waived when not timely presented to the ALJ); *Finnigan Corp. v. Int’l Trade Comm’n*, 180 F.3d



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1354, 1362–63 (Fed. Cir. 1999) (finding argument waived when not presented in petition for review of an ALJ’s determination).

**c. Obviousness**

Apple’s last argument relates to the Commission’s adoption of the Final ID’s rejection of Apple’s Lumidigm-based obviousness defense. The Final ID found that “persons of ordinary skill in the art would not have expected to successfully measure blood oxygen in a wristwatch at the time of the Poeze patents,” and thus a person of ordinary skill in the art would not have modified the wrist-watch embodiment of Lumidigm according to Apple’s theory to arrive at the claimed inventions. *See* Final ID at 115–18 (including n. 44) (discussing the limiting preamble of claim 22 of the ’502 patent).<sup>2</sup>

Apple asserts that, “[w]hen concluding that a patent claim is not invalid, it is impermissible to require the prior art to enable more than is required by the claim itself.” Mtn. at 14; *see also id.* at 14–18. Apple argues that the Commission found that “the asserted claims of the ’648 and the ’502 patent were not obvious because the prior art reference provided by Apple (Lumidigm) does not enable taking an ‘oxygen saturation’ measurement ‘at the wrist.’” *Id.* at 17 (citing Final ID at 113–17). Apple then asserts that the Commission erred because “none of the claims for which a violation was found recites or requires taking a measurement at the wrist.” *Id.* According to Apple, if the device “described in the prior art could take a blood oxygen measurement anywhere on the body, it would anticipate or render obvious the claimed subject matter.” *Id.* at 18. Finally, Apple asserts that the Commission found that “Lumidigm does

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<sup>2</sup> The Final ID’s reasoning likewise applied to the other asserted claims (except for claim 12 of the ’501 patent), as Apple also alleged that those claims were obvious over combinations of references involving Lumidigm’s wrist-watch embodiment and those claims also recite measuring blood oxygen. *See, e.g.,* Final ID at 128, 140, 142.

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describe taking blood oxygen measurements via a user-worn device,” so it must anticipate or render obvious the claims at issue. *Id.* (emphasis omitted).

Apple has not shown an “admittedly difficult legal question” because Apple is challenging a simple factual finding of the Commission. *See* Oppn. at 18–20. Moreover, Apple misconstrues the Final ID, and Apple’s argument (also presented in its petition for review of the Final ID) was already considered and rejected by the Commission. *See* RPet. at 15–20. Neither the Final ID nor the Commission required Lumidigm to enable more than the asserted patent claims. *See* Oppn. at 18–20. Rather, the Commission properly analyzed Lumidigm and other evidence to determine if a person of ordinary skill in the art would have been motivated to modify Lumidigm’s wristwatch to measure oxygen saturation to arrive at the alleged invalidating device with a reasonable expectation of success. *See, e.g.,* Final ID at 113–18; *see also, e.g., id.* at 118 n.44 (“The evidence regarding the difficulty in achieving blood oxygen measurements at the wrist, as discussed above, also shows the lack of clear and convincing evidence of a reasonable expectation of success for the asserted obviousness arguments.”). While measuring oxygen saturation at the wrist is not claimed, Apple chose to base its invalidity theory on measuring blood oxygen saturation at the wrist being taught or suggested by Lumidigm to a person of ordinary skill in the art at the time of the invention.

Here, the Commission properly found that Lumidigm, alone or combined with knowledge in the art at the time of the invention, did not enable measuring oxygen saturation at the wrist, and therefore a person of ordinary skill in the art would not have reasonably expected success at arriving at the device serving as the basis of Apple’s obviousness theory. *See, e.g.,* Final ID at 113–18, 124, 128, 132, 140, 142; Oppn. at 19; *ActiveVideo Networks, Inc. v. Verizon*

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*Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012); *Raytheon Techs. Corp. v. GE Co.*, 993 F.3d 1374, 1380–81 (Fed. Cir. 2021).

## **2. Whether Apple Will Be Irreparably Injured Absent a Stay**

Apple argues that it faces “unquantifiable harm if it is barred from importing its current Apple Watch models into the United States during the pendency of its appeal,” specifically a loss of “goodwill” and “significant damage to its reputation.” Mtn. at 18; *see also id.* at 18–19. Apple additionally asserts that a “sudden dearth of Apple Watch products will inevitably harm the public’s perception of Apple,” and “Apple will undoubtedly lose goodwill it has built over the decades of providing high quality, innovative electronics in a timely manner, leading potential customers not to purchase any watch at all.” *Id.* at 19. Apple further argues that “allowing the Commission’s orders to go into effect will provide fodder to support Complainants’ baseless assertions that Apple improperly copied Complainants’ technology—fundamentally tarnishing Apple’s signature strong reputation as an innovator.” *Id.* (internal quotations omitted).

The Commission finds that Apple has not shown that it will suffer irreparable harm such that this *Standard Havens* factor supports a stay. As Complainants point out, Apple’s alleged irreparable injuries are “pure attorney argument supported by no evidence,” Oppn. at 22, and are thus unpersuasive. *See, e.g., Tobacco Heating Articles*, Comm’n Op. at 14 (“Philip Morris offers vague and unsupported declarations with generalizations, such as alleged loss of goodwill . . . without supporting calculations or substantiation of underlying assumptions. . . . Philip Morris’s motion is therefore speculative and unsupported.”) (internal citation omitted); *Certain Marine Sonar Imaging Devices, Including Downscan & Sidescan Devices, Prods. Containing the Same, & Components Thereof*, Inv. No. 337-TA-921 (Modification), Comm’n Op. Denying Garmin Respondents’ Emergency Motion for Stay Pending Appeal at 13 (Oct. 20, 2016) (“Garmin has

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failed to cite to any evidence concerning the purported harms caused by issuance of the [remedial order].”). Here, Apple presented no evidence supporting the nature or extent of any alleged harm it faces from a denial of a stay of the remedial orders, which affect just a portion of one product line<sup>3</sup> in Apple’s large suite of product and service offerings. Additionally, statements regarding Apple’s copying of Masimo’s technology and Apple’s pattern of “efficient infringement” are already in the public record. *See Oppn.* at 22.

**3. Whether a Stay Will Substantially Injure Other Parties Interested in the Proceeding**

Apple asserts that “Complainants will not suffer cognizable harm if the Commission stays its orders pending appeal.” *Mtn.* at 20. Apple points out that Complainants are suing it for infringement of the same patents in district court and thus Complainants can obtain monetary relief. *Id.* Apple further argues that Complainants are unlikely to suffer any harm from a stay because Masimo’s W1 Watch is not selling “in the United States in any meaningful quantity.” *Id.*; *see also id.* at 20–21. Apple adds that, even if the W1 Watch was selling “in material quantities in the United States, Mr. Kiani<sup>4</sup> has stated on a recent quarterly earnings call that ‘customers that we’re targeting are people who have chronic illnesses and need a serious . . . measurement.’” *Id.* at 21 (citation omitted).

The Commission finds that Complainants would suffer some harm by granting the stay. The Commission has explained that a complainant “will be irreparably injured by a stay that denies its patents the full term to which they are entitled.” *Certain Lens-Fitted Film Packages*,

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<sup>3</sup> The Apple Watch SE is not affected by the Commission’s remedy. *See, e.g., Certain Light-Based Physiological Measurement Devices & Components Thereof*, Inv. No. 337-TA-1276, Comm’n Op. at 94, 118 (Nov. 14, 2023).

<sup>4</sup> Mr. Joe Kiani is Masimo’s chief executive officer.

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Inv. No. 337-TA-406, Comm’n Op. at 17 (June 28, 1999); *Tobacco Heating Articles*, Comm’n Op. at 16; *see also Agric. Tractors*, Comm’n Op. at 16. That said, the Commission notes that Complainants do not contest Apple’s assertion that Masimo is not selling its W1 Watch in the United States in any meaningful quantity and also does not intend to widely market that product in the United States, opting instead to market a different, not yet released product in the United States. *See* Oppn. at 22–23; *see also* Mtn. at 20–21. Thus, Complainants would not appear to miss out on substantial revenue in the event of a stay. The Commission further notes that Complainants’ parallel pending district court proceeding provides a forum for Complainants to attempt recovery of monetary damages for infringement. *See Certain Dig. Models, Dig. Data, & Treatment Plans for Use in Making Incremental Dental Appliances*, Inv. No. 337-TA-833, Comm’n Op. at 8 (June 11, 2014) (granting stay of remedial orders). While Congress has provided for “Commission relief [to be] ‘in addition to’ relief provided by the district courts,” the presence of a parallel pending district court proceeding, although not alone sufficient to support a stay, has at times been considered relevant by the Commission for this *Standard Havens* factor. *See id.* at 8 & n.8 (“Accordingly, the mere availability of a district court proceeding is not enough to tilt the harms factors in favor of a stay.”); *see also Tobacco Heating Articles*, Comm’n Op. at 15–16. Thus, overall, the Commission finds that Complainants would suffer some injury from the grant of a stay pending appeal.

#### **4. Where the Public Interest Lies**

Apple argues that “allowing the Commission’s orders to go into effect before Customs [and Border Protection] has approved Apple’s proposed redesigned Watch would be detrimental to many consumers’ daily lives.” Mtn. at 22. Apple further argues that “the lack of a stay would also pose an immediate setback for medical research, where Apple Watch plays a critical role.” *Id.*; *see also id.* at 22–23. Apple additionally declares that “without a stay, the Commission’s

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orders will have a significant, negative effect on the economy in general.” *Id.* at 23. Apple points to the number of its U.S.-based employees and to the presence of U.S.-based components suppliers, developers, and accessory manufacturers. *Id.* at 23–24. Apple also makes a vague reference to a “detrimental impact on the healthcare field.” *Id.* at 24. Apple additionally asserts that “removing Apple Watches from the market virtually overnight may both ‘lessen competition’ and—at least in the short term—allow other companies to potentially impose higher prices.” *Id.*

The Commission finds that the public interest does not support a stay pending appeal, and in fact counsels against granting a stay. As Complainants point out, Apple’s arguments have already been considered and rejected by the Commission in the Commission’s final determination. *See* Oppn. at 23–24. In addition, the “public interest favors the protection of intellectual property rights by excluding infringing products.” *Tobacco Heating Articles*, Comm’n Op. at 16–17 (quoting *Certain X-Ray Breast Imaging Devices & Components Thereof*, Inv. No. 337-TA-1063, ID at 281 (July 26, 2018) and citing *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1306 (Fed. Cir. 2012); *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013)).

**5. Balancing the *Standard Havens* Factors**

Apple has not shown that the weighing of the *Standard Havens* factors, as modified via Commission jurisprudence, favors granting a stay pending appeal. Apple has failed to show the existence of an admittedly difficult legal question. Additionally, Apple has not shown that it will suffer irreparable harm from allowing the orders to remain in place pending appeal. Furthermore, Complainants would suffer some harm from a stay. Moreover, the public interest lies with denying a stay. Overall, after weighing the *Standard Havens* factors, the Commission has determined that Apple’s motion should be denied.

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**B. Potential Government Shutdown**

Apple also asserted in its Motion that a potential federal government shutdown may prevent or inhibit the Presidential review process of the Commission’s remedial order and thus the Commission should exercise its statutory authority to order a stay because “justice requires” it exercise its “inherent power” to order a stay “to protect the integrity of its own proceedings.” Mtn. at 25–27 (citing 5 U.S.C. § 705; *Tokyo Kikai Seisakusho, Ltd. v. U.S.*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)); *see also* 19 U.S.C. § 1337(j). However, after Apple filed its motion, the federal government was funded through at least the sixty-day period of Presidential review. Accordingly, this part of Apple’s motion is denied as moot.

**V. CONCLUSION**

Apple’s motion to stay enforcement of the exclusion and cease and desist orders pending appeal and/or in light of a potential government shutdown is denied.

By order of the Commission.



Lisa R. Barton  
Secretary to the Commission

Issued: January 3, 2024

**CERTAIN LIGHT-BASED PHYSIOLOGICAL  
MEASUREMENT DEVICES AND COMPONENTS  
THEREOF**

**Inv. No. 337-TA-1276**

Certificate of Service – Page 1

**CONFIDENTIAL CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served upon the following parties as indicated, on **December 20, 2023**.



Lisa R. Barton, Secretary  
U.S. International Trade Commission  
500 E Street, SW, Room 112  
Washington, DC 20436

**On Behalf of Complainants Masimo Corporation and  
Cercacor Laboratories, Inc.:**

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